

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

					Intro	duction Type:		New Item		Final Version			Date:	7/10/	2020
			PRODUCT INFORMATIO	N						SPECIAL HANDL	ING AND ST	ORAGE REQ	JIREMENTS	*	
	AuroMedics Pharma I					Application:	:	ANDA	a. Temperature – India	cate the USP temper	rature range f				
Application Number for NDA		PMA/510(k)(med de	¿vice):	212965					Tempera	ature Range		Controlled R	oom – betwe	een 20 and 25	C (68° – 77° F
	968961354	I								emperature Range Re	equirement	-			i
Proprietary Name (If Applicate Selling Unit NDC:	ble) and Established I 55150-342-25	Name: Ver	rapamil HCl Injection USP Individual Unit NDC:	55150-342-0	1	UPC: '35515	0342259		(w	rite in)		Store at 20°	- 25° C (68° -	- 77° F). [See	
UDI	33130-342-23		CVX Code:	33130-342-0		Code:	00342239		Is this p	roduct to be shipped	to customers	on ice?		No	
Description:	Verapamil HCl Injection	on USP 5 mg/2 mL	(2.5 mg/mL) Single Dose Vial (25 Via	ils)		<u> </u>			\$ I	roduct to be shipped				No	
Active Ingredient(s):		Verapamil							b. Contact for tempera	ature excursion que	stions:	Steve Lucas			
URL for Additional Product In	nformation:								Number	r:		732-823-412			
Address:	279 Princeton-Hightstown Road					2:			Group E-mail: slucas@aurobindousa.com						
City:	East Windsor			State: Email:	NJ	Żip:	085	520	a Cuasial resultations	No					
Key Contact: Phone Number:	888-238-7880			Fax:						c. Special regulations for product in any states?  Special returns requirements for this product?  No					
Product Therapeutic Classific						-			1						
									d. Store product (unit					No	
ADDITIONA	L PRODUCT INFORM	ATION			PRODUCT I	DESCRIPTION IN	NFORMAT	ION	Protect	product (unit of sale	e) from light?			No	
Is the Product									e. Shelf life:				Ų	18	Months
a legend device?		No.		Size:	2	2 mL x 25's SDV			Initial s	helf life at launch (if	different):		Ų		Months
reverse numbered? co-licensed?		No No			-					(	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only	—	Strength:	5	5 mg/2 mL (2.5 mg	g/mL)						,		
Is the Product		Neither		Dosage For	m:	LIQUID			Unit of				NDC selling	unit?	
									x	Bottle Box/Carton		55150-342-2	g. 1 Box of 1	0 Viole)	
If Unit Dose, is item bar coded	d to unit dose for hospi	ital scanning?			Ī.					Ampule		(vviite-iii, e.	y. I box of f	J Vidis)	
If Unit Dose NDC, indicate ND	DC here:			Product Sha	ipe:	/ial Pack				Glass		Minimum o	rder quantity	/?	Yes
		I. a.		Product Col	or:					Tube					
Country of Origin		India	<del></del>		-				<u> </u>	Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of wh	ich package t	vne?
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:							Vial Powder Sql		100,	Each	on paonago t	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
					_					Vial Power Multi			Inner/Carton	ı/Pack	
			FOR GENERIC DRUG PROD	UCTS						Other: Write In	_	1	Case		
			TOR SENERIO DROST ROD												
				Au	thorized Gene			eneric, other section		PHAF	RMACY ORDE	ER / BILL UN	T		
I. Orange Book Rating:	AP					fields a	are not app	olicable	Rec. sell unit to custo		_	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Brand?: Isoptin Injection									25 vials		x	Each			
		DRUG S	UPPLY CHAIN SECURITY ACT (DS	CSA) INFORMATION					(Write-in, e.g. 1 Vial)			-	Gram Milliliter		
			(	,									, willinger		
Does supplier meet DSCSA d		urer?	Yes	GLN:						ITEM A	IND PACKING	INFORMAT	ON		
Is product exempt from DSCS	SA?		No								Dimensions (US msmts.)				
If yes, select exemption: Other exemption - Write in:										Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Is product repackaged?			No		inal product p	purchased direct	t		Item:	0.54378	3.54	1.97	3.54	24.687252	25 vials
Is product sold by manufactu			No	from mfr?						0.54576	3.34	1.57	3.34	24.007232	25 Viais
Has FDA granted waiver/exce	eption/exemption for	product?	No	If yes, attach do	cumentation	from FDA.			Box/Carton/Bundle/ Inner Pack:	3.52686	11.2598	4.7244	3.9763	211.522456	150 vials
			GTIN PRODUCT INFORMA	TION					Case:						
			Sal	eable						15.296	12.2047	10.2362	8.6614	1082.06654	600 vials
				Jnit		Quanti		IN-14	Pallet:	1256.732	48	56.18	40	107865.6	48000 vials
Serialized? If not, when?	Yes		x Item x Box/Carton/Bundle/Inner Pack	x 2D x 2D		Linear 25 Linear 150		355150342259 355150342250	UPC:	Case:	5035515034	12254	<u> </u>		
Items aggregated?			x Case	x 2D		Linear 600		355150342254	or c.	003551503					
			x Pallet	<b>X</b> 2D	2D Linear 48000 2D Linear			355150342258		Carton:					
									COST INFORMATION			WHOLESALER USE ONLY:			Y:
		_	<del></del>	2D 2D		Linear			Regular Cost			Vendor #:			
				2D		Linear	1		Invoice Cost (WAC) (\$	5)	\$500.00	Whsl. Code	#:		
									Federal Excise Tax Pe		, ,,,,,,,,,,	Fineline Co			
									As of date:						
				NIEET (000)											
*Please provide any additional	al information on pag	e 2	Attach copy of SAFETY DATA S	OUEE1 (ODO) OF DOD DO		p. 3 for Designa			Signatu				Muramredd	y penchalaiah	
	avimation on pay	~			OCC HEW	P. O IOI DESIGNA	u Diop	op oy.	Signatu			L	uramicuu	/ Portorialaidil	



### **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? 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 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? 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 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: SP# 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) 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 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: 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: 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:		Purchase order daily receipt cut off time by supplier					
a. EDI		Cut off time:					
b. Autofax	Fax Number:						
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: Supplier's Customer Service Number:		Ships for second day receipt: Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #:	Name:	Ships regular ground for 3-10 days receipt.					
Contracted of 2 company / contact //.	Phone:						
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	ocessing				
Expedited freight fees billed with each order		Overnight receipt available:	or o				
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:					
Drop Ship miscellaneous fees billed:		Days of week overnight is available:	Monday				
Comments:			Tuesday				
			Wednesday Thursday				
			Friday				
			i nady				
		Priority Overnight receipt available:					
Cla	ss of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select YES if sold to retail p	harmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:		PO Receipt Cut off time:					
Restricted to hospital, clinics, and physicia		Order receipt method:  Phone:  Phone #:					
Restricted from US territories? (explain in o	comments)	Fax: Fax #:					
Comments:		EDI: Overnight Fees apply:					
		Other fees apply:					
Other Data In	formation Required to Process PO:	Return Instructions					
	iorniation required to Frocess FO.						
Patient Procedure Date: Physician Name:		Contact # if product is received damaged:  Is product returnable for credit:					
Physician/Clinic Phone #		URL/Link to returns policy:					
Physician State License #		Special regulations or returns requirements for this product in cer	tain states?				
Physician/Clinic DEA #:		If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:		·					
	Miscellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?					
		Is product order for restocking purposes?					



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

					Introd	duction Type:		New Item		Final Version			Date:	7/10/	2020
			PRODUCT INFORMATION	ON						SPECIAL HANDL	ING AND STO	ORAGE REQ	UIREMENTS	*	
	AuroMedics Pharma I					Application:	: [	ANDA	a. Temperature – Indic	ate the USP temper	ature range f				
Application Number for ND	A/ANDA/BLA (drug); F	PMA/510(k)(med de	vice):	212965					Tempera	ature Range		Controlled R	.oom – betwe	een 20 and 25	C (68° – 77° F
	968961354	To a								emperature Range Re	equirement	-			i
Proprietary Name (If Applicat Selling Unit NDC:	ble) and Established I 55150-343-05	Name: Vera	apamil HCl Injection USP Individual Unit NDC:	55150-343-0	1	UPC: '355150	0343056		(wi	rite in)		Store at 20°	- 25° C (68°	- 77° F). [See	
UDI	00100 040 00	l .	CVX Code:	00100 040 0	MVX		0343030		Is this pr	roduct to be shipped t	to customers	on ice?		No	
Description:	Verapamil HCl Injection	on USP 10 mg/4 mL	(2.5 mg/mL) Single Dose Vial (5 Via	als)						roduct to be shipped t				No	•
Active Ingredient(s):		Verapamil							b. Contact for tempera	ture excursion ques	stions:	Steve Lucas			
URL for Additional Product Ir	nformation:								Name: Number	:		732-823-412			
Address:	ess: 279 Princeton-Hightstown Road				Address				Group E	-mail:		slucas@aur	obindousa.co	om	
City:	East Windsor			State: Email:	NJ	Žip:	0852	20		No					
Key Contact: Phone Number:	888-238-7880				Fax: 732-355-9449					c. Special regulations for product in any states?  Special returns requirements for this product?  No				•	
Product Therapeutic Classific									opeoid.						
•									d. Store product (unit	of sale) upright?				No	
ADDITIONA	L PRODUCT INFORM	ATION			PRODUCT D	DESCRIPTION IN	IFORMATIO	ON	Protect	product (unit of sale	e) from light?			No	
Is the Product					_				e. Shelf life:					18	Months
a legend device? reverse numbered?		No No		Size:	6	mL x 5's SDV			Initial sl	helf life at launch (if	different):				Months
co-licensed?		No		0	_					(	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only		Strength:	1	0 mg/4 mL (2.5 m	ng/mL)								
Is the Product		Neither		Dosage For	n: L	IQUID			Unit of S	-		What is the 1 box of 5 vi	NDC selling	unit?	
					L				x	Bottle Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	d to unit dose for hospi	ital scanning?		Product Sha	ino:	/ial Pack				Ampule		(	g		
If Unit Dose NDC, indicate NI	DC here:			r roudet one	ipe.	iai i ack				Glass		Minimum o	rder quantity	/?	Yes
Country of Origin		India	$\neg$	Product Col	or:				-	Tube Vial Liquid Sgl					
Is this product covered under the Trade Agreements Act (TAA)?						Vial Liquid Multi		If Yes, how	many of wh	ich package t	ype?				
is this product covered under the Trade Agreements Act (TAA)? No.							Vial Powder Sql			Each					
									L	Vial Power Multi Other: Write In		1	Inner/Cartor Case	i/Pack	
			FOR GENERIC DRUG PROD	UCTS						Culoi: Willo III	T		,0000		
											_		_		
	F			Au	horized Gene		norized Gen are not appl	neric, other section			RMACY ORDE				
	AP	Isoptin Injection				noide a	по пос арра	iloubio	Rec. sell unit to custor Multi vials (			Rx billing u	nit to pharm Each	acy:	
II. Generic Equivalent to What Brand?: Isoptin Injection								(Write-in, e.g. 1 Vial)				Gram			
		DRUG SU	JPPLY CHAIN SECURITY ACT (DS	CSA) INFORMATION								х	Milliliter		
Does supplier meet DSCSA d	lafinitian of manufact		Yes	GLN:						ITEM A	ND BYCKING	INFORMAT	ION		
Is product exempt from DSCS			No	GLN.						II EM A	AND PACKING INFORMATION				
If yes, select exemption:									Weight Lbs.		nsions (US m		Volume	# Pieces:	
Other exemption - Write in:			No	W. W					1		Depth	Height	Width	(Cube)	
Is product repackaged? Is product sold by manufactu	ırer's exclusive distril	butor?	No	from mfr?	nai product p	ourchased direct			Item:						
Has FDA granted waiver/exce			No	If yes, attach do	cumentation	from FDA.			Box/Carton/Bundle/	0.29502	7.09	1.57	3.54	39.404802	5 vials
				=:01:					Inner Pack:	0.29302	7.03	1.57	3.34	33.404002	J viais
			GTIN PRODUCT INFORMA	leable					Case:	7.531	15.354	9.055	9.449	1313.69891	100 vials
				Jnit		Quantit	ty GTIN	N-14	Pallet:	575.282	48	58.54	40	112396.8	7200 vials
Serialized?	Yes	x		<b>X</b> 2D		inear 1					40	36.34	40	112330.0	
If not, when?		x		x x 2D x 2D	X 2D Linear				UPC:	Case: Carton:					
Items aggregated?		- ×		x 2D 2D		inear 7200		55150343057		Carton.					
				2D	L	Linear 7200 7035			COST	INFORMATION			WHOLESAL	ER USE ONL	Y:
				2D		inear									
				2D 2D		inear	+ +		Regular Cost Invoice Cost (WAC) (\$	١	\$150.00	Vendor #: Whsl. Code	#-		
					٠				Federal Excise Tax Pe		ψ130.00	Fineline Co			
									As of date:						
									<u> </u>						
*Please provide any addition	al information on	0.2	Attach copy of SAFETY DATA	SHEET (SDS) or non ha		ACKAGE INSERT p. 3 for Designat							Muramrada	ly nanchalaish	
*Please provide any addition	ai iiiioiiiiatioii on pag	C 4.			See new	p. 5 IOI Designat	rea prop 9	niip Oilly.	Signatu	16.			wurannedd	ly penchalaiah	



### **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? 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 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? 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 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: SP# 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) 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 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: 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: 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:		Purchase order daily receipt cut off time by supplier					
a. EDI		Cut off time:					
b. Autofax	Fax Number:						
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: Supplier's Customer Service Number:		Ships for second day receipt: Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #:	Name:	Ships regular ground for 3-10 days receipt.					
Contracted of 2 company / contact //.	Phone:						
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	ocessing				
Expedited freight fees billed with each order		Overnight receipt available:	or o				
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:					
Drop Ship miscellaneous fees billed:		Days of week overnight is available:	Monday				
Comments:			Tuesday				
			Wednesday Thursday				
			Friday				
			i nady				
		Priority Overnight receipt available:					
Cla	ss of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select YES if sold to retail p	harmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:		PO Receipt Cut off time:					
Restricted to hospital, clinics, and physicia		Order receipt method:  Phone:  Phone #:					
Restricted from US territories? (explain in o	comments)	Fax: Fax #:					
Comments:		EDI: Overnight Fees apply:					
		Other fees apply:					
Other Data In	formation Required to Process PO:	Return Instructions					
	iorniation required to Frocess FO.						
Patient Procedure Date: Physician Name:		Contact # if product is received damaged:  Is product returnable for credit:					
Physician/Clinic Phone #		URL/Link to returns policy:					
Physician State License #		Special regulations or returns requirements for this product in cer	tain states?				
Physician/Clinic DEA #:		If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:		·					
	Miscellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?					
		Is product order for restocking purposes?					