

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

						Inti	roduction Type:	:	New Item		Final Version			Date:	19.11	.2019		
				PRODUCT INFORMATION							SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	<b>*</b>			
Company Name:	Auromedics Pharma	LLC					Applicati	ion:	ANDA	a. Temperature – Indi	cate the USP temper	ature range	for this produ	ıct.				
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(me	ed device):		206670						rature Range				en 20 and 25	C (68° – 77° I		
DUNS:	968964687				<u> </u>					Other T	emperature Range Re	equirement						
Proprietary Name (If Applica	ble) and Established	Name:	Vecuroniun	n Bromide for Injection (10 mg p	er Vial)						vrite in)							
Selling Unit NDC:	55150-235-10			Individual Unit NDC:	55150-235			150235100								•'		
UDI				CVX Code:		MV	X Code:			Is this p	product to be shipped	to customers	on ice?		No			
Description:	Vecuronium Bromide	for Injection (10	mg per Vial	)						Is this p	product to be shipped	to customers	on dry ice?		No	•		
							b. Contact for temperature excursion questions:											
										Name:			Steve Lucas					
URL for Additional Product I Address:	nformation: 279 Princeton-Hightsi	www.auromedi	ics.com			Addres	. 2.			Numbe			888-238-788					
City:	East Windsor	lown Roau			State		Zip:	085	520	Group E-mail: pvg@aurobindousa.com								
Key Contact:	Last Willason				Emai			000	320	c. Special regulations	for product in any s	states?			No			
Phone Number:	888-238-7880				Fax:	732-35	5-9449			Special returns requirements for this product?								
Product Therapeutic Classifi	ication:	Neuromuscula	r Blocking A	gent												•		
										d. Store product (unit					Yes	•		
ADDITIONA	AL PRODUCT INFORM	MATION				PRODUCT	T DESCRIPTION	N INFORMAT	TON	Protec	t product (unit of sale	e) from light?	,		Yes			
Is the Product										e. Shelf life:			24	Months				
a legend device?			No		Size:	Size: 1x10 vials				Initial s	shelf life at launch (if	Month			Months			
reverse numbered?			No No									ORDER INFO	DMATION					
co-licensed?		Direct-Ship On			Strength:	Strength: 10 mg per Vial					•	JKDEK INFO	RWATION					
Is the Product		Direct Grilp Gri	ıı y							Unit of	Sale		What is the	NDC selling	unit?			
					Dosage F	orm:	Injectable dry p	oowder			Bottle		55150-235-1					
If Unit Dose, is item bar code	ed to unit dose for hosp	oital scanning?								х	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	•		
If Unit Dose NDC, indicate N	·				Product S	Shape:					Ampule		Minimum			Vee		
ii Unii Dose NDC, indicate N	DC nere:										Glass Tube		Minimum o	rder quantity	,,,	Yes		
Country of Origin		India			Product C	color:					Vial Liquid Sgl							
Is this product covered under	r the Trade Agreement	s Act (TAA)?			Product In	mprint:				Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:								Vial Powder Sql Each Vial Power Multi Inner/Carton/Pack										
										<u> </u>	Vial Power Multi Other: Write In		1	Inner/Cartor Case	/Pack			
			F	OR GENERIC DRUG PRODUC	TS						Odici: Wille III			oasc				
						Authorized Ge			eneric, other section	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	AP						TIEIC	ds are not app	plicable	Rec. sell unit to custo		_	Rx billing u		acy:			
II. Generic Equivalent to Wha	at Brand?:	Norcuron									ls carton			Each				
		DRUG	G SUPPLY (	CHAIN SECURITY ACT (DSCS	A) INFORMATIO	N				(Write-in, e.g. 1 Vial)				Gram Milliliter				
		5.1.0	0 00: 1 2: 1	5.11.11.02001.11.1.7.01 (2000	,,,	•								Willinger				
Does supplier meet DSCSA		turer?		Yes	GLN:	035515	50000005				ITEM A	ND PACKING	INFORMAT	ION				
Is product exempt from DSC	SA?		No	)								Di	: (IIC					
If yes, select exemption: Other exemption - Write in:											Weight Lbs.	Depth	nsions (US m Height	Width	Volume (Cube)	# Pieces:		
Is product repackaged?			No	)	If Yes, was or	iginal produc	ct purchased di	irect		Item:	0.04045	5.31				\C-1		
Is product sold by manufact				No	from mfr?	•	•				0.64945	5.31	2.36	2.17	27.193572	Vials per can		
Has FDA granted waiver/exc	eption/exemption for	product?		No	If yes, attach	documentati	on from FDA.			Box/Carton/Bundle/	4.249	13.82	2.99	5.75	237.60035	6 Cartons		
				GTIN PRODUCT INFORMATIO	NN .					Inner Pack:	-							
			'	Salea						Case:	18.55	14.764	7.126	12.205	1284.06686	24 Cartons		
				Level Uni			Qua	antity GT	IN-14	Pallet:	067.70	48	44.05	40	00252	1080		
Serialized?			X Ite						355150235100		867.79	46	41.85	40	80352	cartons		
If not, when?				ox/Carton/Bundle/Inner Pack	21				355150235101	UPC:	Case:							
Items aggregated?		_		ase	21 21				355150235105 355150235109		Carton:	355150235	10					
			X Pi	SHOT.	21		Linear 10	703	333130233109	COST	INFORMATION			WHOLESAL	ER USE ONL	Y:		
					20		Linear											
					21	D	Linear			Regular Cost			Vendor #:					
	2D Linear						-	Invoice Cost (WAC) (S	Whsl. Code #:									
										Federal Excise Tax P			Fineline Co	de:				
										As of date:	1/1/2019		4					
			Δ	oob copy of SAECTY DATA OUT	ET (2D2)	hozord lettr :	DACKACE INICI	EDT I ADE:	AND BHOTO OF PRO	DUICT BACKACING	PARCODE		1					
*Please provide any addition	al information on page	no 2	Atta	ach copy of SAFETY DATA SHE	EE I (SDS) OF NON		W p. 3 for Design			DDUCT PACKAGING and Signate				Muramredd	y Penchalaiah			
provide any addition	pag	g~ <del>_</del> .				300 HB	ייי ף. סיוטו טפאונ	a.a.ca Diop	Jane Jany.	Signati				.viui ulliicuu	, . Grioriaiaidi			



### **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: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: SP# 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: 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 http://auromedics.com/policies/return-policy/ No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: 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	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only  Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days  Ships same day for next day receipt:
Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	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:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:  Monday 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 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:	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:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?



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						Intr	roduction Type	):	New Item		Final Version			Date:	19.11	.2019		
				PRODUCT INFORMATION							SPECIAL HANDL	ING AND STO	ORAGE REQ	JIREMENTS	*			
Company Name:	Auromedics Pharma	LLC					Applicat	tion:	ANDA	a. Temperature – Indi	cate the USP temper	ature range f	or this produ	ict.				
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(me	d device):		206670						ature Range				en 20 and 25	C (68° – 77° I		
DUNS:	968964687									Other T	emperature Range Re	equirement				<u>.</u>		
Proprietary Name (If Applica	ble) and Established	Name:	Vecuroniun	n Bromide for Injection (20 mg pe	er Vial)						rite in)							
Selling Unit NDC:	55150-236-20			Individual Unit NDC:	55150-236			5150236206								<u>-</u> '		
UDI				CVX Code:		MV	X Code:			Is this p	roduct to be shipped	to customers	on ice?		No			
Description:	Vecuronium Bromide	for Injection (20	mg per Vial	1)						Is this p	roduct to be shipped	to customers	on dry ice?		No			
							b. Contact for temperature excursion questions:											
URL for Additional Product I	-f	www.auromedi	00.00m							Name: Numbe			Steve Lucas 888-238-788					
Address:	279 Princeton-Hights		CS.COIII			Addres	s 2·			Group			pvg@aurobi					
City:	East Windsor				State		Zip:	085	520	0.045			F - 3					
Key Contact:					Email					c. Special regulations for product in any states?								
Phone Number:	888-238-7880				Fax:	732-35	5-9449			Special	returns requirements	for this produ	ct?		No			
Product Therapeutic Classifi	ication:	Neuromuscula	r Blocking A	gent														
										d. Store product (unit					Yes			
	AL PRODUCT INFORM	IATION				PRODUC	T DESCRIPTIO	N INFORMAT	ION	1	product (unit of sale	e) from light?			Yes			
Is the Product										e. Shelf life:						Months		
a legend device?			No		Size:	Size: 1x10 vials				Initial shelf life at launch (if different):								
reverse numbered? co-licensed?			No No							ORDER INFORMATION								
Is the Product		Direct-Ship On			Strength: 20 mg per Vial					ORDER INFORMATION								
Is the Product					Dosage Fo	orm.	Injectable dry	nouder		Unit of	Sale		What is the	NDC selling	unit?			
					Dosage F	orni.	injectable dry j	powdei			Bottle		55150-236-2					
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?								x	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)			
If Unit Dose NDC, indicate N	DC here:				Product S	hape:					Ampule Glass		Minimum o	der quantit	/?	Yes		
ii Olik Bood NBO, ilididato N	50 11010.				Boots of G						Tube			uoi quantit	· ·	100		
Country of Origin		India			Product C	olor:				Vial Liquid Sgl								
Is this product covered under the Trade Agreements Act (TAA)?							Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each											
No No								Vial Power Multi Inner/Carton/Pack										
											Other: Write In		1	Case	i/i dok			
			F	OR GENERIC DRUG PRODUC	ī\$													
											DUAD	RMACY ORDE	D / DU L LIN	-				
						Authorized Ge		Authorized Ge lds are not app	eneric, other section	<b>5</b> " ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '		RMACY ORDE						
	. Orange Book Rating: AP Reneric Equivalent to What Brand?: Norcuron						Rec. sell unit to custo 10 s vial			Rx billing u	nit to pharm Each	acy:						
ii. Generic Equivalent to What Brand:										s carton			Gram					
		DRU	G SUPPLY	CHAIN SECURITY ACT (DSCS)	) INFORMATION	١				(Write-in, e.g. 1 Vial)				Milliliter				
														ļi				
Does supplier meet DSCSA		turer?	No	Yes	GLN:	035515	50000005				ITEM A	ND PACKING	INFORMAT	ON				
Is product exempt from DSC If yes, select exemption:	SA?		INC	)								Dime	nsions (US m	smts )	Volume			
Other exemption - Write in:											Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:		
Is product repackaged?			No	)		iginal produc	ct purchased di	irect		Item:	1.089	6.5	2.76	2.68	48.0792	Vials per car		
Is product sold by manufactu				No	from mfr?						1.000	0.0	2.70	2.00	10.07 02	vialo por cari		
Has FDA granted waiver/exc	eption/exemption for	product?		No	If yes, attach	documentati	on from FDA.			Box/Carton/Bundle/ Inner Pack:	5.948	14.17	4.13	7.28	426.040888	5 Cartons		
				GTIN PRODUCT INFORMATIO	N					Case:								
				Saleab							13.724	15.157	5.118	15.157	1175.78193	10 cartons		
				Level Unit			_		IN-14	Pallet:	691.801	48	46.34	40	88972.8	480 cartons		
Serialized?		-	X Ite	em X ox/Carton/Bundle/Inner Pack	20				355150236206 355150236207	UPC:	C							
If not, when? Items aggregated?				ase	20				355150236207	III UPC:	Case: Carton:	355150236	206					
items aggregateur		_		allet	20				355150236205		Carton.	000100200	200					
					20	,	Linear			COST	INFORMATION			WHOLESAL	ER USE ONL	.Y:		
					20		Linear						ļ					
	2D Linear							Regular Cost		Vendor #:								
								Invoice Cost (WAC) (\$) \$90.00 Whsl. Code #: Federal Excise Tax Per Unit of Sale Fineline Code:										
										As of date:	1/1/2019		i illellile Co	uc.				
													Ť					
			Atta	ach copy of SAFETY DATA SHE	ET (SDS) or non	hazard letter,	PACKAGE INS	ERT, LABEL	AND PHOTO OF PRO	DUCT PACKAGING and I	BARCODE.							
*Please provide any addition	al information on pag	ge 2.			•		w p. 3 for Desi			Signatu				Muramredd	y 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? 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: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: SP# 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: 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 http://auromedics.com/policies/return-policy/ No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: 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	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only  Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days  Ships same day for next day receipt:
Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	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:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:  Monday 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 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:	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:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?