

Standard Pharmaceutical Product Information (Rx Product Only)

					Introduction	Туре:	New Item		Final Version			Date:				
			PRODUCT INFORMATION						SPECIAL HANDLI	NG AND STO	RAGE REQ	UIREMENTS	•			
Company Name: AuroMedics Pharma LLC Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206206						Temperature Range Cold – between 2 and 8 C (36° – 46° F)										
DUNS:							Other Temperature Range Requirement									
Proprietary Name (If Applicable) and Established Name: ROCURONIUM BROMIDE INJECTION 50 mg/5 mL (10 mg/mL) [MDV]							(write in)									
Selling Unit NDC: 55150-225-05 Individual Unit NDC: UPC: "355150225057"							4									
UDI			CVX Code:		MVX Code:			Is this product to be shipped to customers on ice? Yes								
Description:	ROCURONIUM BROM	MIDE INJECTION 50 mg/5	mL (10 mg/mL) [MDV]					Is this product to be shipped to customers on dry ice? No								
Active Ingredient(s):								b. Contact for tempera	turo eveurcion auec	tions						
Active ingredient(s).								Name:	Steve Lucas							
URL for Additional Product In	nformation:	www.auromedics.com						Number		732-823-4122						
Address:	279 Princeton-Hightst	own Road	Address 2:					Group E	-mail:							
City:	East Windsor			State:	NJ	Zip:	08520									
Key Contact:	888-238-7880			Email:	722 255 0440			c. Special regulations			0	-	No			
Phone Number: Product Therapeutic Classifi			Fax: 732-355-9449					Special	returns requirements f	ror this produc	CT?	-	No			
Froduct Therapeutic Classiii	cation.							d. Store product (unit of	of sale) unright?				Yes			
ADDITIONA	L PRODUCT INFORM	ATION		F	PRODUCT DESCRI	PTION INFORM	IATION		product (unit of sale) from light?		-	No			
Is the Product								e. Shelf life:	,	24 Months			Months			
a legend device?		No							nelf life at launch (if	different):		•	27	Months		
reverse numbered?		No		Size:												
co-licensed?		No		Strength:					0	RDER INFOR	RMATION					
Is the Product		Direct-Ship Only		Outengun.												
Is the Product				Dosage Form	:			Unit of S	-1		10 vials in o	NDC selling	unit?			
								x	Bottle Box/Carton			g. 1 Box of 1) \/iale\			
If Unit Dose, is item bar code	d to unit dose for hospi	tal scanning?						<u> </u>	Ampule		(vviite-iii, e	.g. 1 Dox 01 10	, viais)			
If Unit Dose NDC, indicate NI	DC here:			Product Shap	e:			Glass Minimum order quantity? Yes								
				Product Colo	r:				Tube				•			
Country of Origin		India						Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under	the Trade Agreements	Act (TAA)?		Product Impr	int:				Vial Elquid Multi Vial Powder Sql		ir res, now	Each	cn package t	yper		
								Vial Power Multi 32 Inner/Carton/Pack								
							Other: Write In	-		Case						
			FOR GENERIC DRUG PRODUCT	S						1						
				Auth	orized Generic	*If Authorized	I Generic, other section		PHAR	MACY ORDE	R / BILL UN	IT				
I. Orange Book Rating:	AP			7100	011204 00110110	fields are not							unit to pharmacy:			
II. Generic Equivalent to What Brand?: Zemuron										Each						
								(Write-in, e.g. 1 Vial)		_	Gram					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION												Milliliter				
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0355150000005									ITEM AN	ID BYCKING	INFORMAT	ION				
Is product exempt from DSC			10	GLN.	0333130000003			ITEM AND PACKING INFORMATION								
If yes, select exemption:									Weight Lbs.	Dimen	sions (US n	nsmts.)	Volume	# Pieces:		
Other exemption - Write in:									weight Lbs.	Depth	Height	Width	(Cube)	# Fieces.		
Is product repackaged?			lo Ne	If Yes, was origin from mfr?	al product purchas	sed direct		Item:					0			
Is product sold by manufactu Has FDA granted waiver/exce			No No		umentation from F	DΔ		Box/Carton/Bundle/	0.40200 (Carton	TOS CARTON	105 Carton	10 S CARTOIT	10 S Carton			
rias i DA grantea warver/exe	eption/exemption for [110	ii yes, attacii ace	amentation from t	DA.		Inner Pack:	contains 10 Vials)	5.12	1.97	2.05	20.67712 E Eluto Boy	10		
			GTIN PRODUCT INFORMATION					Case:	18.896	20.276	7.677	12.205	1899.81629	10 Vials =		
			Saleable	Э							rui aea		FUL SEA	320 Vials		
Serialized?		х	Level Unit] D	Linear		GTIN-14 00355150225057	Pallet:	For Sea 599.920 For Air 826.672	For Sea 48 For Air 48	43.39	For Sea 40 For Air 40	83308.8	9600 Vials		
If not, when?			Box/Carton/Bundle/Inner Pack 10s	2D 2D	Linear		10355150225057	UPC:	Case:	1 01 All 40	For Air	1 01 All 40	For Air	For Air		
Items aggregated?			Case	Iner Pack 108 2D	Linear		50355150225052		Carton:	"355150225	057"					
X Pallet					Linear		70355150225056									
				2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ONL	Y:		
1		<u> </u>		2D	Linear						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	r		-		
1	2D Linear 2D Linear					Regular Cost										
<u> </u>					Linear			Federal Excise Tax Pe		\$60.00	Fineline Co					
1								As of date:	6/19/2017							
									•		1					
			tach copy of SAFETY DATA SHEE	T (SDS) or non haz												
*Please provide any addition	al information on pag	e 2.			See new p. 3 for	Designated Dr	op Ship Only.	Signatu	re:							



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 Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: 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: Fax Num	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?						



Standard Pharmaceutical Product Information (Rx Product Only)

					Introduction T	ype:	New Item		Final Version			Date:				
			PRODUCT INFORMATION						SPECIAL HANDLI	NG AND STO	RAGE REQ	JIREMENTS	*			
Company Name: AuroMedics Pharma LLC Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206206							Temperature Range Cold – between 2 and 8 C (36° – 46° F)									
DUNS:							Other Temperature Range Requirement									
Proprietary Name (If Applicable) and Established Name: ROCURONIUM BROMIDE INJECTION 100 mg/10 mL (10 mg/mL) [MDV]								(write in)								
Selling Unit NDC: 55150-226-10 Individual Unit NDC: UPC: "355150226108" UDI CVX Code: MVX Code:							'	ls this product to be shipped to customers as iso?								
	BOOLINGS III II A BBOOL	UDE IN IEOTION (A)	CVX Code:		WVX Code.			Is this product to be shipped to customers on ice? Yes								
Description:	ROCURONIUM BRON	MIDE INJECTION 100 mg/	10 mL (10 mg/mL) [MDV]					Is this product to be shipped to customers on dry ice?								
Active Ingredient(s):								b. Contact for temperature excursion questions:								
								Name:		Steve Lucas						
URL for Additional Product I Address:	Information: 279 Princeton-Hightsto	www.auromedics.com			Address 2:	1		Numbe	732-823-4122							
City:	East Windsor	OWII KOdu		State:		Zip: 085	520	Group E-mail:								
Key Contact:	Edot Willdoor			Email:	140		,20	c. Special regulations	s for product in any st	ates?			No			
Phone Number:	888-238-7880			Fax:	732-355-9449			Special returns requirements for this product?								
Product Therapeutic Classif	ication:															
ADDITIONA	AL PRODUCT INFORM	ATION			PRODUCT DESCRIP	TION INFORMAT	TON	d. Store product (unit					Yes			
	AL PRODUCT INFORM	ATION			PRODUCT DESCRIP	TION INFORMAT	ION	1	t product (unit of sale) from light?		;	No			
Is the Product a legend device?		No						e. Shelf life:	shelf life at launch (if	different).			24	Months Months		
reverse numbered?		No No		Size:				IIIIuai s	sileii ille at laulicii (il i	amerem).				Wolldis		
co-licensed?		No		Strength:				ORDER INFORMATION								
Is the Product		Direct-Ship Only		Outengin.				Unit of Sale What is the NDC selling unit?								
Is the Product				Dosage Form	n:			Unit of	Bottle		10 vials in o		unit?			
Miller Describeration	adda oo baar baar baar	!! O						x	Box/Carton	ı		g. 1 Box of 1	0 Vials)			
If Unit Dose, is item bar code	·	ital scanning?		Product Shar	oe:				Ampule							
If Unit Dose NDC, indicate N	IDC here:								Glass Tube		Minimum o	der quantity	?	Yes		
Country of Origin		India		Product Colo	r:				Vial Liquid Sgl							
				Product Impr	int:			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 32 Inner/Carton/Pack										
						<u> </u>	Vial Power Multi Other: Write In		32	Inner/Carton Case	/Pack					
			FOR GENERIC DRUG PRODU	CTS					Culon Willow	1 '		Cuoo				
										•						
				Auth		*If Authorized Ge fields are not app	eneric, other section	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	AP	7				neids are not app	Silicable	Rec. sell unit to custo	1 1	Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Zemuron					(Write-in, e.g. 1 Vial) Each											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(**************************************				Milliliter				
								,								
Does supplier meet DSCSA is product exempt from DSC			Yes No	GLN:	0355150000005				ITEM AN	ID PACKING	INFORMAT	ON				
If yes, select exemption:	JOA!	· ·	<u> </u>						Dimensions (US msmts.) Volume							
Other exemption - Write in:	:								Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:		
Is product repackaged?			lo Na	If Yes, was origin from mfr?	nal product purchase	ed direct		Item:					0			
Is product sold by manufact Has FDA granted waiver/exc			No No		umentation from FD	Δ		Box/Carton/Bundle/	0.07 143 (Carton	TOS CARTON	TOS CARTON	TO S CARTOIT	TO S CARTOIT			
nas i DA giantea waivenexe	eption/exemption for [product:	110	ii yes, attaon aoc	amentation nom i b	Α.		Inner Pack:	contains 10 Vials)	5.31	2.36 E-Elute Box	2.17 E-Eluto Box	27.193572 E-Fluto Box	10		
			GTIN PRODUCT INFORMATION					Case:	25.598	20.276	7.677	12.205	1899.81629	10 Vials =		
			Salea Level Un			Quantity GT	IN-14	Pallet:	For Sea 800.992	For Sea 48	rui sea	For Sea 40	rui sea	320 Vials		
Serialized?		х	Item City	2D	Linear		355150226108	Pallet:	For Air 1108.173	For Air 48	43.39	For Air 40	83308.8 For Air	9600 Vials		
If not, when?			Box/Carton/Bundle/Inner Pack 10	S 2D	Linear	10355150226105		UPC:	Case:		FOT AIR		FOT AIT	FOT AIT		
Items aggregated?			Case	2D	Linear		355150226103		Carton:	"355150226	108"					
x Pallet 2D Linear 70355150226107 Linear Linear Linear						COS.	T INFORMATION			WHOLESAL	FR USE ONL	γ.				
	2D Linear 2D Lin								WHOLESALER USE ONLY:							
	2D Linear 2D Lin					Regular Cost		Vendor #:								
							Invoice Cost (WAC) () Whsl. Code #:								
								Federal Excise Tax P	er Unit of Sale		Fineline Co	de:				
									6/19/2017							
L								As of date:	6/19/2017			•				
		Af	ttach copy of SAFETY DATA SH	IEET (SDS) or non haz	ard letter, PACKAGE	INSERT, LABEL	AND PHOTO OF PRO	As of date:								



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 Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: 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: Fax Num	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?						