

Standard Pharmaceutical Product Information (Rx Product Only)

						Introduction	Туре:	New Item	х	Final Version			Date:	10.JUL	Y.2020
			PRODUCT INFORMA	TION						SPECIAL HANDL	ING AND STO	ORAGE REQI	UIREMENTS	*	
Company Name: AuroMedics Pharma LLC Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA	r for NDA/ANDA/BLA (drug); PMA/510(k)(med device):			205529				Temperature Range Controlled Room – between 20 and 25 C (68					C (68° – 77° F		
DUNS:	968961354								Other Te	emperature Range Re	equirement				<u>.</u>
Proprietary Name (If Applicable) and Established Name: Oxaliplatin Injection 5 mg/mL									(write in) Store at 20° to 25°C (68° to 77°F);						
Selling Unit NDC:	55150-331-01		Individual Unit NDC:	5515	50-331-01	UPC:	'3551503310	17							II
UDI CVX Code:				MVX Code:			Is this product to be shipped to customers or			on ice?		No			
Description: Oxaliplatin Injection 5 mg/mL, USP (50 mg/10 mL) (SDV) [1's]							Is this pr	oduct to be shipped t	to customers	on dry ice?		No			
													•		
Active Ingredient(s): Oxaliplatin Injection								b. Contact for tempera	ture excursion ques	stions:					
									Name:			Steve Lucas			
URL for Additional Product Information: Address: 279 Princeton-Hightstown Road			1		Address 2:			Number Group E		732-823-4122 slucas@aurobindousa.com					
City:	279 Princeton-Hightstown Road				Address 2:			Group E	-man.		3iucas @ auii	Juli luousa.cc	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Key Contact:	East Windsor				Email:			c. Special regulations	for product in any s	tates?			No		
Phone Number:	888-238-7880				Fax: 732-355-9449				returns requirements		ct?		No	•	
Product Therapeutic Classific									=						•
									d. Store product (unit	of sale) upright?				No	
ADDITIONA	L PRODUCT INFORM	MATION			PRODUCT DESCRIPTION INFORMATION				Protect product (unit of sale) from light?				No		
Is the Product									e. Shelf life:			18 Mont			Months
a legend device?		No	_	Size	Size: 1 x 20 mL Mono SDV Vial								Months		
reverse numbered?		No	_	0.20	1 X 20 IIIL MONO SDV VIAI										
co-licensed?		No Direct-Ship Only	_	Stre	Strength: (50 mg/10 mL) (SDV)				Ĺ	ORDER INFO	RMATION				
Is the Product		Neither	_			-			Unit of S	Sale		What is the	NDC selling	unit?	
is the Froduct		110,010	-	Dosa	age Form:	LIQUID			ll one or c	Bottle		1 box of 1 vi			
If I lait Door is item has and		Caninnan lati.							1	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	•	ontal scanning?		Proc	Product Shape: Vial Pack			Ampule							
If Unit Dose NDC, indicate NI	DC here:			1	Viai Fack			Glass Minimum order quantity? Yes					Yes		
			Proc	Product Color:			Tube Vial Liquid Sgl								
Country of Origin India							Vial Liquid Sgi Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under the Trade Agreements Act (TAA)?			Proc	duct Imprin	t:				Vial Powder Sql		ii 165, ilow	Each	icii package i	ype:	
								Vial Power Multi				Inner/Carton/Pack			
									<u> </u>	Other: Write In	_	1	Case		
FOR GENERIC DRUG PRODUCTS															
					Author	rized Conorio	*If Authorized	Caparia ather section		DHAD	RMACY ORDE	P/RIII IINI	т		
I. Orange Book Rating: AP II. Generic Equivalent to What Brand?:				Authorized Generic *If Authorized Generic, other section fields are not applicable				Rec. sell unit to customer?			Rx billing unit to pharmacy:				
								1 vial			x Each				
II. Generic Equivalent to What Brands.								(Write-in, e.g. 1 Vial)	ai .	_		Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION												Milliliter			
Does supplier meet DSCSA d		turer?	Yes No	GLN:						ITEM A	ND PACKING	INFORMATI	ON		
Is product exempt from DSCS If yes, select exemption:	SA?		INO								Dimer	nsions (US m	ismts)	Volume	
Other exemption - Write in:										Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No	If Yes, w	as original	product purcha	sed direct		Item:	0.15	1.89	3.15	1.57	9.346995	1 vial
Is product sold by manufactu			No	from mf	r?		•			0.15	1.09	3.15	1.57	9.340993	ı viai
Has FDA granted waiver/exce	eption/exemption for	product?	No	If yes, at	ttach docur	mentation from F	DA.		Box/Carton/Bundle/	2.102	10.28	4.13	4.37	185.534468	12 vials
			GTIN PRODUCT INFOR	MATION					Inner Pack:						
				Saleable					Case:	4.997	11.22	9.646	5.315	575.232458	24 vials
			Level	Unit			Quantity	GTIN-14	Pallet:	652.618	·				
Serialized?	Yes	х	Item	х	2D	Linear	1	00355150331017			48	43.58	40	83673.6	3720 vials
If not, when?		x				Linear	12	30355150331018	UPC:	Case:	5035515033				
Items aggregated?	ns aggregated?						Carton: 00355150331017								
					Linear	3720	70355150331016	COST INFORMATION			WHOLESALER USE ONLY:				
		-		- 	2D 2D	Linear				IN ORWATION			MICHEGAL	LA USE UNL	
					2D	Linear			Regular Cost			Vendor #:			
					2D Linear							Whsl. Code #:			
								•	Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
									As of date:						
												<u> </u>			
*Please provide any addition:	al information on no	na 2	Attach copy of SAFETY DAT	I A SHEET (SDS) o		rd letter, PACKAG			DUCT PACKAGING and B	ARCODE.			Muramradd	v nenchalaich	



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. Cvtotoxic? 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? Oxidizer No Inorganic 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 If Yes, is it managed with a pharmacy registry? Cargo 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: 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: Phone Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) No If yes, indicate which: 888-238-7880 Is it a scheduled listed chemical product?: No 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? If so, which states? Other requirements? Comments? Restricted to hospital, clinics, and physician offices only: No 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 d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees:	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: 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: 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: 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?



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					Introduction T	ype:	New Item		Final Version			Date:	10.JUL	1.2020
			PRODUCT INFORMATION	ON					SPECIAL HANDLI	NG AND STO	DRAGE REQU	JIREMENTS	*	
Company Name:	AuroMedics Pharma LLC Application: ANDA er for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 205529						a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F							
* *		WA/310(k)(Illed device).		200029				•	=		- Controlled IV	DOIN DOING	cii 20 ana 20	0 (00 11 1
DUNS: Proprietary Name (If Applicate	968961354		n Injection 5 mg/mL, USP						mperature Range Re		Store at 20°	- 0E0C (CO0	4a 770F).	
Selling Unit NDC:	55150-332-01	varne: Oxalipiati	Individual Unit NDC:	55150-332-01	UPC:	'35515033201	4	(WI	ite in)		Stole at 20	10 23 C (00	ю / г г),	
UDI	00.00 002 01		CVX Code:	00.00 002 01	MVX Code:	33313033201	*	Is this pr	oduct to be shipped to	o customers o	on ice?		No	
Description: Oxaliplatin Injection 5 mg/mL, USP (100 mg/20 mL) (SDV) [1's]							Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice?					No		
Active Ingredient(s): Oxaliplatin Injection							b. Contact for temperature excursion questions:							
URL for Additional Product Ir	-fti							Name: Number	_		Steve Lucas 732-823-412	2		
Address:	279 Princeton-Hights	own Road			Address 2:	1		Group E			slucas@auro		m	
City:	East Windsor	omi rioda		State:		Zip:	08520	0.000	· man.		oldodo Gadir	,Diridododi.oc		
Key Contact:				Email:				c. Special regulations	for product in any s	tates?			No	
Phone Number:	888-238-7880			Fax:	Fax: 732-355-9449			Special i	returns requirements	for this produc	ct?		No	
Product Therapeutic Classific	cation:							=						
								d. Store product (unit	of sale) upright?				No	
ADDITIONA	L PRODUCT INFORM	ATION			PRODUCT DESCRIP	TION INFORM	ATION	Protect	product (unit of sale) from light?			No	
Is the Product								e. Shelf life:					18	Months
a legend device?		No		Size: 1 x 20 mL Mono SDV Vial				Initial sh	nelf life at launch (if	different):				Months
reverse numbered?		No		Size.	1 X ZU IIIL	WOOTO SDV VIA								
co-licensed?		No		Strength: (100 mg/20 mL) (SDV)					C	RDER INFO	RMATION			
Is the Product		Direct-Ship Only			(· · · · · · · · · · · · · · · · · · ·	, (,								
Is the Product		Neither		Dosage Form	: LIQUID			Unit of S			What is the 1 box of 1 vi		unit?	
								x	Bottle Box/Carton		(Write-in, e.		0 Viale)	
If Unit Dose, is item bar coded	d to unit dose for hosp	ital scanning?							Ampule		(**************************************	g. 1 DOX 01 1	o viais)	
If Unit Dose NDC, indicate ND	DC here:			Product Shap	e: Vial Pack			Glass Minimum order quantity? Yes						
·				Product Color					Tube					
Country of Origin		India		Froduct Color	٠.			Vial Liquid Sgl						
Is this product covered under	the Trade Agreements	Act (TAA)?		Product Impri	int:			Vial Liquid Multi If Yes, how many of which package type?						
· ·	· ·	No No						Vial Powder Sql Each Vial Power Multi Inner/Carton/Pack						
								IJ <u></u>	Other: Write In		- 1	inner/Carton Case	/Pack	
			FOR GENERIC DRUG PROD	LICTS					Other. Write III	1	- '	Case		
Authorized Generic *If Authorized Generic, other section														
					orized Generic				PHAR	MACY ORDE	ER / BILL UNI	T		
I. Orange Book Rating:	AP				orized Generic	*If Authorized fields are not a		Rec. sell unit to custor		MACY ORDE	R / BILL UNI		acy:	
I. Orange Book Rating: II. Generic Equivalent to Wha					orized Generic			1 vi	mer?	MACY ORDE		nit to pharm Each	асу:	
				Auth	orized Generic				mer?	MACY ORDE		nit to pharm Each Gram	асу:	
		DRUG SUPPL'	Y CHAIN SECURITY ACT (DS	Auth	orized Generic			1 vi	mer?	MACY ORDE		nit to pharm Each	асу:	
II. Generic Equivalent to Wha	t Brand?:		· ·	Auth	orized Generic			1 vi	mer? al]	Rx billing u	nit to pharm Each Gram Milliliter	acy:	
	tt Brand?:	urer?	Y CHAIN SECURITY ACT (DS No	Auth	orized Generic			1 vi	mer? al]		nit to pharm Each Gram Milliliter	асу:	
II. Generic Equivalent to Wha Does supplier meet DSCSA d Is product exempt from DSCS If yes, select exemption:	tt Brand?:	urer?	No	Auth	orized Generic			1 vi	ner? al ITEM AI	ND PACKING	Rx billing u	nit to pharm Each Gram Milliliter ON smts.)	Volume	# Pieces
II. Generic Equivalent to Wha Does supplier meet DSCSA d Is product exempt from DSC! If yes, select exemption: Other exemption - Write in:	tt Brand?:	urer?	No No	Auth GCSA) INFORMATION GLN:		fields are not a		1 vi (Write-in, e.g. 1 Vial)	mer? al	ND PACKING	Rx billing u	nit to pharm Each Gram Milliliter		# Pieces:
II. Generic Equivalent to Wha Does supplier meet DSCSA d Is product exempt from DSC If yes, select exemption. Other exemption - Write in: Is product repackaged?	t Brand?: definition of manufact SA?	urer?	No No	GCSA) INFORMATION GLN: If Yes, was origin	orized Generic	fields are not a		1 vi	ner? al ITEM AI	ND PACKING	Rx billing un x INFORMATI	nit to pharm Each Gram Milliliter ON smts.)	Volume	# Pieces:
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	urer?	No No No No	GLN: If Yes, was origin from mtr?	al product purchase	d direct		1 vi (Write-in, e.g. 1 Vial)	ner? al ITEM Al Weight Lbs.	Dimer Depth	Rx billing un x INFORMATI nsions (US m Height	eit to pharm Each Gram Milliliter ON smts.) Width	Volume (Cube) 9.346995	
II. Generic Equivalent to Wha Does supplier meet DSCSA d Is product exempt from DSC If yes, select exemption. Other exemption - Write in: Is product repackaged?	t Brand?: definition of manufact SA? urer's exclusive distri	urer?	No No	GLN: If Yes, was origin from mtr?		d direct		ttem: Box/Carton/Bundle/	ner? al ITEM Al Weight Lbs.	ND PACKING Dimer Depth	Rx billing un x INFORMATI nsions (US m Height	nit to pharm Each Gram Milliliter ON smts.) Width	Volume (Cube)	
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	urer?	No No No No No No	GLN: If Yes, was origin from mfr? If yes, attach doc	al product purchase	d direct		(Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack:	mer? al ITEM Al Weight Lbs. 0.15 2.102	Dimer Depth 1.89	Rx billing un x INFORMATI usions (US m Height 3.15 4.13	enit to pharm Each Gram Milliliter ON smts.) Width 1.57 4.37	Volume (Cube) 9.346995 185.534468	1 vial
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	urer?	No No No No No No No The product information of	GLN: If Yes, was origin from mfr? If yes, attach doc	al product purchase	d direct		ttem: Box/Carton/Bundle/	ITEM AI Weight Lbs. 0.15	Dimer Depth	Rx billing u x INFORMATI asions (US m Height 3.15	eit to pharm Each Gram Milliliter ON smts.) Width	Volume (Cube) 9.346995	1 vial
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	urer?	No No No No No No Sainternation	GLN: If Yes, was origin from mfr? If yes, attach docurron	al product purchase	d direct Quantity	applicable	(Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack:	mer? al Weight Lbs. 0.15 2.102 4.997	Dimer Depth 1.89 10.28 11.22	Rx billing un x INFORMATI sions (US m Height 3.15 4.13 9.646	Each Gram Milliliter ON Width 1.57 4.37 5.315	Volume (Cube) 9.346995 185.534468 575.232458	1 vial 12 vials 24 vials
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	butor? product?	No No No No No No Sal Level	GLN: If Yes, was origin from mfr? If yes, attach doc TION eable Juit X 2D	al product purchase umentation from FD.	d direct Quantity 1 Quantity	applicable GTIN-14 10355150332014	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	mer? al Weight Lbs. 0.15 2.102 4.997 652.618	Dimer Depth 1.89 10.28 11.22 48	X X X X X X X X X X	enit to pharm Each Gram Milliliter ON smts.) Width 1.57 4.37	Volume (Cube) 9.346995 185.534468	1 vial
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	butor? product?	No No No No No No No Sal Level Item Box/Cartor/Bundle/Inner Pack	If Yes, was origin from mfr? If yes, attach documents of yes, attach do	al product purchase umentation from FD. Linear Linear	d direct Quantity 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	STIN-14 00355150332014 00355150332015	Item: Box/Cartor/Bundle/ Inner Pack: Case:	mer? al Weight Lbs. 0.15 2.102 4.997 652.618 Case:	Dimer Depth 1.89 10.28 11.22 48 5035515033	Rx billing ur x INFORMATI asions (US m Height 3.15 4.13 9.646 43.58 32019	Each Gram Milliliter ON Width 1.57 4.37 5.315	Volume (Cube) 9.346995 185.534468 575.232458	1 vial 12 vials 24 vials
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	outor? product?	No No No No Sal Level ltem BowCarton/Bundle/Inner Pack Case	GCSA) INFORMATION GLN: If Yes, was origin from mfr? If yes, attach doc: TION eable Jnit X 2D X 2D X 2D	al product purchase umentation from FD. Linear Linear Linear	d direct A. Quantity 1 1 12 24 [1]	GTIN-14 00355150332014 00355150332015 00355150332019	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	mer? al Weight Lbs. 0.15 2.102 4.997 652.618	Dimer Depth 1.89 10.28 11.22 48	Rx billing ur x INFORMATI asions (US m Height 3.15 4.13 9.646 43.58 32019	Each Gram Milliliter ON Width 1.57 4.37 5.315	Volume (Cube) 9.346995 185.534468 575.232458	1 vial 12 vials 24 vials
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II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	outor? product?	No No No No Sal Level ltem BowCarton/Bundle/Inner Pack Case	GCSA) INFORMATION GLN: If Yes, was origin from mfr? If yes, attach doc: TION eable Jnit X 2D X 2D X 2D	al product purchase umentation from FD. Linear Linear Linear	d direct A. Quantity 1 1 12 24 [1]	GTIN-14 00355150332014 00355150332015 00355150332019	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC:	mer? al Weight Lbs. 0.15 2.102 4.997 652.618 Case:	Dimer Depth 1.89 10.28 11.22 48 5035515033	Rx billing ur x INFORMATI usions (US m Height 3.15 4.13 9.646 43.58 32019 32014	nit to pharm Each Gram Milliliter ON smts.) Width 1.57 4.37 5.315	Volume (Cube) 9.346995 185.534468 575.232458	1 vial 12 vials 24 vials 3720 vials
II. Generic Equivalent to Wha 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	t Brand?: definition of manufact SA? urer's exclusive distri	outor? product?	No No No No Sal Level ltem BowCarton/Bundle/Inner Pack Case	If Yes, was origin from mfr? If yes, attach documents of yes, attach do	al product purchase umentation from FD. Linear Linear Linear Linear Linear Linear Linear	d direct A. Quantity 1 1 12 24 [1]	GTIN-14 00355150332014 00355150332015 00355150332019	Item: Box/Cartor/Bundle/ Inner Pack: Case: Pallet: UPC:	mer? al Weight Lbs. 0.15 2.102 4.997 652.618 Case: Carton:	Dimer Depth 1.89 10.28 11.22 48 5035515033	Rx billing ur x INFORMATI usions (US m Height 3.15 4.13 9.646 43.58 32019 32014	nit to pharm Each Gram Milliliter ON smts.) Width 1.57 4.37 5.315	Volume (Cube) 9.346995 185.534468 575.232458 83673.6	1 vial 12 vials 24 vials 3720 vials
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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. Cvtotoxic? 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? Oxidizer No Inorganic 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 If Yes, is it managed with a pharmacy registry? Cargo 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: 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: Phone Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) No If yes, indicate which: 888-238-7880 Is it a scheduled listed chemical product?: No 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? If so, which states? Other requirements? Comments? Restricted to hospital, clinics, and physician offices only: No 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 d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees:	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: 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: 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: 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?