

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014	gust 2014 Introduction Type: New Item			Item		Fi	nal Version		Date:				
		F	RODUCT INFORMATION						SPECIAL HAN	IDLING AND ST	ORAGE REQU	REMENTS*	
Company Name:	Company Name: AuroMedics Pharma LLC Application: ANDA						4	a. Temperatur	e – Indicate the	e USP temperat	ure range for th	nis product.	
Application Number for				-				1.	Freezer – betw	een -25 and -10	C (-13° – 14° F)		
Rx Product/Proprietary N	Name:	EPTIFIBATIDE	INJECTION 20 mg/10 mL	(2 mg/ml)				YES II.	Cold – betwee	n 2 and 8 C (36°	– 46° F)		
NDC:	55150-219-10	2		UPC:	355150219100					en 8 and 15 C (4	,		
CVX Code:				MVX Code:						,	0 and 25 C (68°	– 77° F)	
Description:	EPTIFIBATIDE INJE	CTION 20 mg/10) ml (2 mg/ml)						allows for exc	ursions between	15 and 30 C (59	9° – 86° F)	
Decomption.	El TILIBATION INCL	011011 20 mg/ 10	/ IIIL (Z IIIg/IIIL)						Avoid Excessi	ve Heat – above	40 C (>104° F)		
Active ingredients:										rature Range Re	, ,		
									(write in)		•		
URL for Additional Produ	uct Information:							V	II. No Requirem	ient			
Address:	6 Wheeling Road			Address 2:				b. Contact for	temperature e	xcursion quest	ions:		
City:	Dayton		State:	NJ	Zip: 088	810		Name:	Steve Lucas				
Key Contact:			Email:						732-823-4122				
Phone Number:	888-238-7880		Fax:	732-355-9449						to customers of		Yes	
		FOR	GENERIC DRUG PRODUC	CTS				Is this produc	ct to be shipped	to customers of	n dry ice?	No	=,
I. Orange Book Rating:	AP		II. Brand Name:										
III. Generic Equivalent fo	or Brand:	Integrilin	•					c. Special regu	ulations for pro	oduct in certain	states?	No	
	DRU	G SUPPLY CHA	AIN SECURITY ACT (DSCS	SA) INFORMATI	ON			Special retur	ns requirements	s for this produc	t?	No	
Does supplier meet DSC	SA definition of manu	facturer?	Yes	DUNS:	968961354				•	·			•
Is product exempt from I		No			00001001			d. Store produ	uct (unit of sale	e) upright?		No	
			_					Protect product (unit of sale) from light?				•	
If yes, select exemption: Other exemption - Write in:								Frotect pro	duct (dilit of s	ale, iroin light:		110	-
			If Voc. was origina	l product purch	accod direct from mfr?			e. Shelf life:	24	Months			
Is product repackaged? No Is product sold by manufacturer's exclusive distributor?			If Yes, was original product purchased direct from mfr? No					e. Sileli ille.		fe at launch (if	different):		Months
Are any waivers granted			No	If yes, attach	documentation from FD	Α			minutal official in	io at laailoii (ii	amoromy.		IIIOIIIII0
	·	ADDITIONAL	PRODUCT INFORMATION						ITEM AND	PACKING INFO	ORMATION		
In the Dundant	Direct Ship Item			ORDER INFOR	MATION					ensions (US m		Valores	
Is the Product Legend Device?	Direct Ship item	No	Unit of Sale		IDC selling unit?			Weight Lbs.	Depth	Height	Width:	Volume (Cube)	# Pieces:
State Control?		No	Bottle		e carton (Mono)				Бериі	rieigiit	Width.	(Gube)	
ARCOS reportable?		No	x Box/Carton	one via in on	o danton (mono)		Item:						
Co-Licensed?		No	Ampule	(Write-in, e.g.	. 1 Box of 10 Vials)		Box/		1.41 Inches	1.73 Inches	1.41 Inches		1 Vial
Controlled Substance?		No	Glass				Carton:		1.41 Iliches	1.73 IIICHES	1.41 IIICHES		
Schedule No.?			Tube	Minimum ord	ler quantity?	Yes	Case:		19.48 Inches	6.88 Inches	15.35 Inches		240 cartons
(incl. N for non-narcot	,		Vial Liquid Sgl	16.36									(60x1)x4
Controlled Substance Co Hazardous Material/Cyto		No No	Vial Liquid Multi Vial Powder Sql	if Yes, now m	nany of which package ty Each	ype?	Pallet:		48 Inches	44.61 Inches	40 Inches		20 Shippers
Tidada acus maiorium cyto	riomo rigom :		Vial Power Multi	240	Inner/Carton/Pack			Case:			l	I	
Is Item			Other: Write In		Case		UPC:	Carton:	35515021910	0			
If Unit Dose, is item bar co													
hospital scanning?	dea to unit dose for									COST INFO	RMATION		
nospitai scarring:	ded to unit dose for		PHARMACY ORDER	/ BILL UNIT	Other Product	t informatio	11			COST IN C			· T D
Is it reverse numbered?	ded to unit dose for		PHARMACY ORDER . Rec. sell unit to custom		Size/Strength/Form:	t Informatio	on	Regular Cos	t Per Unit of			Federal Exc	ise Tax Per
	oded to unit dose for					t Informatio	on	Regular Cos Sale			st (WAC) (\$)		rise Tax Per of Sale
Is it reverse numbered?	SALER USE ONLY:			ner?		t Informatio		•					
Is it reverse numbered?			Rec. sell unit to custom	ner?	Size/Strength/Form: Product Shape:	ar/colorless		•		Invoice Co			
Is it reverse numbered?			Rec. sell unit to custom (Write-in, e.g. 1	ner?	Size/Strength/Form: Product Shape:			•		Invoice Co	st (WAC) (\$)		
Is it reverse numbered? WHOLE Vendor #:			(Write-in, e.g. 1 Rx billing unit to pharm Each Gram	ner?	Size/Strength/Form: Product Shape:			•		Invoice Co	st (WAC) (\$)		
Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:			Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each	ner?	Product Shape: Product Color:			•		Invoice Co	st (WAC) (\$)		
Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	SALER USE ONLY:	uttach copy of SA	(Write-in, e.g. 1 Rx billing unit to pharm Each Gram	ner?	Product Color: Product Imprint:	ar/colorless		Sale	9 (\$)	Invoice Co: \$15 As of date:	st (WAC) (\$)		
Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	SALER USE ONLY:	.,	Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram Milliliter	l Vial) lacy:	Product Color: Product Imprint:	ar/colorless		Sale	9 (\$)	Invoice Co: \$15 As of date:	st (WAC) (\$)		



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

	MATERIAL	$_{ t L}$ HAZARD CLASSIFICATION and	TRANSPORTATIO	DN					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label	No No		Hazardous Waste	dentification			I		
c. Contact Hazard?	No	EPA Hazardous Wast	e Code:						
d. Does this product require special clean-up instructions?	No								
(If yes, attach SDS with special instructions.)									
e. Does the product contain DEHP?	No								
Is this product regulated for shipment by the DOT?	No	(if yes, answer a-d below ar a. DOT Hazard Class	nd provide SDS)						
Is this a reportable quantity?		b. UN/ID Number							
RQ Threshold:		c. Packing Group							
Is this a marine pollutant?		d. Inhalation Hazard?							
Is this product shipped utilizing an authorized DOT exception or Special Perr (if yes, identify method below)	mit?	_							
Limited Quantity			ADDITIONAL	. PRODUCT IN	FORMATIO	N - Serializatio	n		
Consumer Commodity, ORM-D				Level		How?		GTIN-14	
Small Quantity (49 CFR 173.4)		Serialized?		Item	2D	Linear	RFID	10355150219107	
Special Permit; DOT-SP		If not, when?		Box/Carton	2D	Linear	RFID	00355150219100	
Special Provision (listed in Column 7 of 49 CFR 172.101);		Items aggregated to case?		Case	2D	Linear	RFID	50355150219105	
SP#			<u> </u>	Pallet	2D	Linear	RFID	70355150219109	
Is the product restricted for air shipment? If so, indicate restriction:			REM	S or REGISTR	Y RESTRIC	TIONS			
Passenger Cargo Passenger & Cargo		Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:							
ADD'L STORAGE INFORMATION				2)					
ADD'L STORAGE INFORMATION		Comments / Details: (For examp	ole, iPledge program	1?)					
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer									
Aerosol Class; Identify NFPA Storage Level:				RETURN INS	TRUCTION	S			
	_	Contact tel. # if product received							
		Is product returnable for credit	t:						
Listed Chemical (List I or II) (Indicate or Write-in below):		URL/Link to returns policy:							
Ephedrine		Special regulations or returns red			n states?				
Pseudoephedrine		If so, which states? Other require	ements? Comments	s?					
Phenylpropanolamine									
Iodine (≥2.2%) Other:									
CLASS OF TRADE RESTRICTION:				ADDITIONAL I	NEODMATI	ON			
				ADDITIONALI	NFURMATI	UN			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		If Unit Dose NDC, indicate NDC							
Restricted to retail pharmacy only:			MISCELLANEOL	JS NOTES and	/or Image o	f Product Bard	ode:		
Restricted to hospital, clinics, and physician offices only:									
Restricted from US territories? (explain in comments)									
Comments:									



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 Fax Number: d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
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
	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:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Order receipt method: Phone: Phone #: Fax #:
Comments:	EDI:
	Overnight Fees apply: Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS: REMS Program Manager Name: Phone:	Contact # if product is received damaged:
Supplier Manages REMS registry exclusively:	Is product returnable for credit: URL/Link to returns policy:
Wholesale distributor support:	Special regulations or returns requirements for this product in certain states?
Provider Name:	If so, which states? Other requirements? Comments?
Site Enrollment Number assigned by Supplier: DEA #: PCPDP #: NPI #:	
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:	



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© August 2014			Introduction Type: New Item				F	Final Version		Date:			
		PRO	DDUCT INFORMATION						SPECIAL HAN	NDLING AND ST	TORAGE REQU	IREMENTS*	
Company Name:	Company Name: AuroMedics Pharma LLC Application: ANDA						A	a. Temperature – Indicate the USP temperature range for this product.					
Application Number for NDA/ANDA/BLA, Med Device:								. Freezer – betw	reen -25 and -10	C (-13° – 14° F)			
Rx Product/Proprietary I									I. Cold – betwee		,		
NDC:	55150-218-99	El Til IB/TIBE III	102011014 70 mg/100 m	UPC:	355150218998				II. Cool – betwee	`	,		
CVX Code:				MVX Code:				l ——		`	20 and 25 C (68°	– 77° F)	
Description:	EPTIFIBATIDE INJE	TION 75 mg/100	ml (0.75 mg/ml)		-						15 and 30 C (59	,	
Description.	EF THIBATIDE INSE	5110N 75 Hig/100	ine (0.75 mg/me)								e 40 C (>104° F)	,	
Active ingredients:									/I. Other Temper		, ,		
J									(write in)				1
URL for Additional Prod	uct Information:								/II. No Requirem	nent			_
Address:	6 Wheeling Road			Address 2:				b. Contact for	r temperature e	xcursion quest	tions:		
City:	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas	·			
Key Contact:			Email:					Number:	732-823*4122	2			
Phone Number:	888-238-7880		Fax:	732-355-9449				Is this produ	uct to be shipped	d to customers o	n ice?	Yes	_
		FOR G	NERIC DRUG PRODUC	CTS				Is this produ	uct to be shipped	d to customers o	n dry ice?	No	
I. Orange Book Rating:	AP		II. Brand Name:										_
III. Generic Equivalent fo		Integrilin						c. Special reg	julations for pro	oduct in certain	states?	No	
	DRU	G SUPPLY CHAIN	SECURITY ACT (DSCS	SA) INFORMATI	ON			Special retu	irns requirement	s for this produc	+12	No	_
Dago cumplior most DCC			,	<u>'</u>	968961354			oposia. Foto	oroquiromoni	5 . c. t p. caac			_
Does supplier meet DSC Is product exempt from		No	Yes	DONG.	900901334			d Store prod	lust funit of cal	a) upright?		No	
			_									_	
If yes, select exemption Other exemption - Wri						7		Protect pro	oduct (unit of s	ale) from light?	?	No	_
•	ite in:									1			
Is product repackaged? No				al product purch	nased direct from mi	fr?		e. Shelf life:	24	Months fe at launch (if	P. (************************************		
Is product sold by manufacturer's exclusive distributor?													
<u> </u>						n FDA			illitiai sileli li	ic at launon (ii	unierent).		Months
Are any waivers granted	for product ID/barcod	e?	No		documentation fron	n FDA				,	,		Months
		e?				n FDA			ITEM AND	PACKING INFO	ORMATION		Months
Is the Product	for product ID/barcod Direct Ship Item	e? ADDITIONAL PR	No ODUCT INFORMATION	ORDER INFOR	RMATION	n FDA		Weight Lbs.	ITEM AND	PACKING INFO	ORMATION ismts.)	Volume	# Pieces:
Is the Product Legend Device?		e? ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale	ORDER INFOR	RMATION IDC selling unit?	n FDA		Weight Lbs.	ITEM AND	PACKING INFO	ORMATION	Volume (Cube)	
Is the Product Legend Device? State Control?		ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle	ORDER INFOR	RMATION	n FDA	Item:	Weight Lbs.	ITEM AND	PACKING INFO	ORMATION ismts.)		
Is the Product Legend Device?		e? ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton	ORDER INFOR What is the N One vial in one	RMATION IDC selling unit? e carton (Mono)	n FDA	Item:	Weight Lbs.	ITEM AND Dim Depth	PACKING INFo	ORMATION esmts.) Width:		# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable?		ADDITIONAL PR No No No	No ODUCT INFORMATION Unit of Sale Bottle	ORDER INFOR What is the N One vial in one	RMATION IDC selling unit?	n FDA		Weight Lbs.	ITEM AND	PACKING INFO	ORMATION ismts.)		
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?		ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule	ORDER INFOR What is the N One vial in one	MATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials)	n FDA	Box/ Carton:	Weight Lbs.	Dim Depth 2.16 Inches	PACKING INFO nensions (US m Height	ORMATION (Issmts.) Width:		# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFOR What is the N One vial in one (Write-in, e.g.	MATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials) ler quantity?	Yes	Box/	Weight Lbs.	ITEM AND Dim Depth	PACKING INFo	ORMATION esmts.) Width:		# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N One vial in one (Write-in, e.g.	MATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials) ler quantity? nany of which packa	Yes	Box/ Carton:	Weight Lbs.	Dim Depth 2.16 Inches	PACKING INFO nensions (US m Height	ORMATION (Issmts.) Width:		# Pieces: 1 Vial 40 cartons
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m	EMATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials) ler quantity? nany of which packa Each	Yes	Box/ Carton: Case: Pallet:		Dim Depth 2.16 Inches 12.20 Inches	D PACKING INFO nensions (US m Height 1.73 Inches 10.82 Inches	ORMATION USINTS.) Width: 2.16 Inches 10.62 Inches		# Pieces: 1 Vial 40 cartons (10x1)x4
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N One vial in one (Write-in, e.g.	MATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials) ler quantity? nany of which packa	Yes	Box/ Carton: Case:	Weight Lbs. Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches	1.73 Inches 10.82 Inches 40.67 Inches	ORMATION USINTS.) Width: 2.16 Inches 10.62 Inches		# Pieces: 1 Vial 40 cartons (10x1)x4
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance CC Hazardous Material/Cyto	Direct Ship Item Lic) Direct Ship Item	ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m	MATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials) ler quantity? hany of which packa Each Inner/Carton/Pack	Yes	Box/ Carton: Case: Pallet:	Case:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches	1.73 Inches 10.82 Inches 40.67 Inches	ORMATION USINTS.) Width: 2.16 Inches 10.62 Inches		# Pieces: 1 Vial 40 cartons (10x1)x4
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Ct Hazardous Material/Cytolls Item	Direct Ship Item Lic) Direct Ship Item	ADDITIONAL PR	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m	e carton (Mono) 1 Box of 10 Vials) Ider quantity? Inany of which packate Each Inner/Carton/Pack Case	Yes	Box/ Carton: Case: Pallet: UPC:	Case:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches	1.73 Inches 10.82 Inches 40.67 Inches	ORMATION Issmts.) Width: 2.16 Inches 10.62 Inches 40 Inches		# Pieces: 1 Vial 40 cartons (10x1)x4
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	Direct Ship Item Lic) Direct Ship Item	ADDITIONAL PR NO	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m	e carton (Mono) 1 Box of 10 Vials) Ider quantity? Inany of which packate Each Inner/Carton/Pack Case	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches	PACKING INFO Densions (US m Height 1.73 Inches 10.82 Inches 40.67 Inches	ORMATION Usmts.) Width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	Direct Ship Item Lic) Direct Ship Item	ADDITIONAL PR NO	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m	e carton (Mono) 1 Box of 10 Vials) Ider quantity? Inany of which packate Each Inner/Carton/Pack Case Other Pro	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 35515021899	PACKING INFO Densions (US m Height 1.73 Inches 10.82 Inches 40.67 Inches	ORMATION Issmts.) Width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered?	Direct Ship Item Lic) Direct Ship Item	ADDITIONAL PR NO	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m 40 / BILL UNIT	e carton (Mono) 1 Box of 10 Vials) 1 Box of 10 Vials) 1 Box of the packa Each Inner/Carton/Pack Case Other Pro Size/Strength/Fort	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 35515021899	PACKING INFO Densions (US m Height 1.73 Inches 10.82 Inches 40.67 Inches	ORMATION Usmts.) Width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Ct Hazardous Material/Cytols Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered?	Direct Ship Item Licito Dode: Distoric Agent? Direct Ship Item	NO N	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m 40 / BILL UNIT	e carton (Mono) 1 Box of 10 Vials) 1 Box of 10 Vials) 1 Box of 10 Vials) 1 Box of 10 Vials 2 Box of 10 Vials 1 Box of 10	Yes ge type? duct Information:	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 35515021899	1.73 Inches 10.82 Inches 40.67 Inches COST INFO	ORMATION Usmts.) Width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered?	Direct Ship Item Licito Dode: Distoric Agent? Direct Ship Item	NO N	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m 40 / BILL UNIT	e carton (Mono) 1 Box of 10 Vials) 1 Box of 10 Vials) 1 Box of the packa Each Inner/Carton/Pack Case Other Pro Size/Strength/Fort	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 35515021899	1.73 Inches 10.82 Inches 40.67 Inches COST INFO	ORMATION Usints.) Width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cot Hazardous Material/Cytolls Item If Unit Dose, is item bar cothospital scanning? Is it reverse numbered? WHOLE Vendor #:	Direct Ship Item Licito Dode: Distoric Agent? Direct Ship Item	NO N	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m 40 / BILL UNIT	e carton (Mono) 1 Box of 10 Vials) 1 Box of 10 Vials) 1 Box of 10 Vials) 1 Box of 10 Vials 2 Box of 10 Vials 1 Box of 10	Yes ge type? duct Information:	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 35515021899	1.73 Inches 10.82 Inches 40.67 Inches COST INFO	ORMATION Usints.) Width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Licito Dode: Distoric Agent? Direct Ship Item	NO N	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m 40 / BILL UNIT	e carton (Mono) 1 Box of 10 Vials) Ider quantity? Ider quan	Yes ge type? duct Information:	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 35515021899	1.73 Inches 10.82 Inches 40.67 Inches COST INFO	ORMATION Usints.) Width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Licic Dode: Stock Agent? Direct Ship Item	NO N	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram Milliliter	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m 40 / BILL UNIT ner? I Vial) hacy:	MATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials) der quantity? hany of which packa Each Inner/Carton/Pack Case Other Pro Size/Strength/Fort Product Shape: Product Color: Product Imprint:	Yes ge type? duct Information: clear/colorless	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 355150218990 st Per Unit of Ite (\$)	1.73 Inches 10.82 Inches 40.67 Inches COST INFO Invoice Co	ORMATION Ismts.) Width: 2.16 Inches 10.62 Inches 40 Inches ORMATION Ist (WAC) (\$)	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item	NO N	No ODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram	ORDER INFOR What is the N One vial in one (Write-in, e.g. Minimum ord If Yes, how m 40 / BILL UNIT her? I Vial) hacy:	MATION IDC selling unit? e carton (Mono) 1 Box of 10 Vials) der quantity? hany of which packa Each Inner/Carton/Pack Case Other Pro Size/Strength/Fort Product Shape: Product Color: Product Imprint:	Yes ge type? clear/colorless ERT, LABEL AN	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches 355150218990 st Per Unit of Ite (\$)	1.73 Inches 10.82 Inches 40.67 Inches COST INFO Invoice Co	ORMATION Ismts.) Width: 2.16 Inches 10.62 Inches 40 Inches ORMATION Ist (WAC) (\$)	(Cube)	# Pieces: 1 Vial 40 cartons (10x1)x4 36 Shippers



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

	MATERIAL	L HAZARD CLASSIFICATION and	TRANSPORTATIO)N				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label	No No		Hazardous Waste	Identification			I	
c. Contact Hazard?	No	EPA Hazardous Waste	e Code:					
d. Does this product require special clean-up instructions?	No							
(If yes, attach SDS with special instructions.)								
e. Does the product contain DEHP?	No							
Is this product regulated for shipment by the DOT?	No	(if yes, answer a-d below ar a. DOT Hazard Class	nd provide SDS)					
Is this a reportable quantity?		b. UN/ID Number						
RQ Threshold:		c. Packing Group						
Is this a marine pollutant?		d. Inhalation Hazard?						
Is this product shipped utilizing an authorized DOT exception or Special Period (if yes, identify method below)	mit?							
Limited Quantity			ADDITIONAL	PRODUCT IN	FORMATIO		n	
Consumer Commodity, ORM-D				Level		How?		GTIN-14
Small Quantity (49 CFR 173.4)		Serialized?		Item	2D	Linear	RFID	10355150218995
Special Permit; DOT-SP		If not, when?		Box/Carton	2D	Linear	RFID	00355150218998
Special Provision (listed in Column 7 of 49 CFR 172.101);		Items aggregated to case?		Case	2D	Linear	RFID	50355150218993
SP#				Pallet	2D	Linear	RFID	70355150218997
Is the product restricted for air shipment? If so, indicate restriction:			REMS	S or REGISTR	Y RESTRIC	TIONS		
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:							
ADD'L STORAGE INFORMATION			I. :Di.d	2)				
		Comments / Details: (For examp	ie, iPiedge program	1?)				
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer								
Aerosol Class; Identify NFPA Storage Level:				RETURN INS	TRUCTION	S		
		Contact tel. # if product received	damaged:					
		Is product returnable for credit	:					
Listed Chemical (List I or II) (Indicate or Write-in below):		URL/Link to returns policy:						
Ephedrine		Special regulations or returns rec			n states?			
Pseudoephedrine		If so, which states? Other require	ements? Comments	.?				
Phenylpropanolamine								
lodine (≥2.2%) Other:								
				ADDITIONAL	NEODMATI	ON		
CLASS OF TRADE RESTRICTION:				ADDITIONAL I	NFORMATI	ON		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		If Unit Dose NDC, indicate NDC	here:					
Restricted to retail pharmacy only:			MISCELLANEOU	JS NOTES and	or Image o	f Product Bard	ode:	
Restricted to hospital, clinics, and physician offices only:								
Restricted from US territories? (explain in comments)								
Comments:								



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 Fax Number: d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
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
	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:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Order receipt method: Phone: Phone #: Fax #:
Comments:	EDI:
	Overnight Fees apply: Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS: REMS Program Manager Name: Phone:	Contact # if product is received damaged:
Supplier Manages REMS registry exclusively:	Is product returnable for credit: URL/Link to returns policy:
Wholesale distributor support:	Special regulations or returns requirements for this product in certain states?
Provider Name:	If so, which states? Other requirements? Comments?
Site Enrollment Number assigned by Supplier: DEA #: PCPDP #: NPI #:	
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:	



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014	August 2014 Introduction Type:			lew Item		F	inal Version		Date:				
		Р	RODUCT INFORMATION						SPECIAL HAN	NDLING AND ST	TORAGE REQU	REMENTS*	
Company Name:	Company Name: AuroMedics Pharma LLC Application: ANDA						Α]	a. Temperatur	e – Indicate th	e USP temperat	ture range for th	nis product.	
Application Number for						I		1.	Freezer – betw	reen -25 and -10	C (-13° – 14° F)		
Rx Product/Proprietary N	Namo:	EPTIFIBATIDE	INJECTION 200 mg/100	ml (2 mg/ml)				YES II.	Cold - betwee	n 2 and 8 C (36°	° _ 46° F)		
NDC:	55150-220-99	El TII ID/TIBE	11102011011 200 111g/ 100 1	UPC:	355150220991					en 8 and 15 C (4	,		
CVX Code:				MVX Code:						,	20 and 25 C (68°	– 77° F)	
Description:	EPTIFIBATIDE INJE	CTION 200 mg/1	00 ml (2 mg/ml)								15 and 30 C (59	,	
Description.	EI III IBATIBE INGE	011014 200 mg/1	oo me (z mg/me)					□ v			e 40 C (>104° F)	,	
Active ingredients:										rature Range Re			
_									(write in)		•		
URL for Additional Produ	uct Information:							v	II. No Requirem	nent			_
Address:	6 Wheeling Road			Address 2:				b. Contact for	temperature e	xcursion quest	ions:		
City:	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas	-			
Key Contact:			Email:						732-823-4122				
Phone Number:	888-238-7880		Fax:	732-355-9449)					d to customers o		Yes	-
		FOR (GENERIC DRUG PRODU	CTS				Is this produ	ct to be shipped	d to customers o	n dry ice?	No	_
I. Orange Book Rating:	AP		II. Brand Name:			-	<u> </u>						
III. Generic Equivalent fo	or Brand:	Integrilin		II.				c. Special regi	ulations for pro	oduct in certain	states?	No	
	DRU	G SUPPLY CHA	IN SECURITY ACT (DSC	SA) INFORMATI	ION		•	Special retur	ns requirement	s for this produc	t?	No	-
Does supplier meet DSC	°CA definition of manu	ineturor?	Yes	DUNS:	968961354								-
Is product exempt from I		No	165	DONO.	900901334			d Store prod	uct (unit of cal	a) upright?		No	
•			_										-
If yes, select exemption:								Protect pro	duct (unit of s	ale) from light?	,	No	-
Other exemption - Write in:						1				1			
Is product repackaged?				al product purc	hased direct from mf	r?		e. Shelf life:	24	Months	-1:66		1
			Is product sold by manufacturer's exclusive distributor? No						initiai sneif ii	fe at launch (if	amerent):		Months
Are any warvers granted	Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA												
					documentation from	II DA			ITEM AND	DACKING INE	ORMATION		
			PRODUCT INFORMATION							PACKING INFO			
Is the Product	Direct Ship Item	ADDITIONAL F	PRODUCT INFORMATION	ORDER INFOR	RMATION			Weight Lbs.	Dim	ensions (US m	smts.)	Volume	# Pieces:
Legend Device?	Direct Ship Item	ADDITIONAL F	PRODUCT INFORMATION Unit of Sale	ORDER INFOR	RMATION NDC selling unit?			Weight Lbs.				Volume (Cube)	# Pieces:
Legend Device? State Control?	Direct Ship Item	No No	Unit of Sale Bottle	ORDER INFOR	RMATION		Item:	Weight Lbs.	Dim	ensions (US m	smts.)		# Pieces:
Legend Device?	Direct Ship Item	No No No	Unit of Sale Bottle Box/Carton	ORDER INFOR What is the M	RMATION NDC selling unit? e carton (Mono)		Item:	Weight Lbs.	Dim Depth	nensions (US m Height	width:		
Legend Device? State Control? ARCOS reportable?	Direct Ship Item	No No	Unit of Sale Bottle	ORDER INFOR What is the M	RMATION NDC selling unit?			Weight Lbs.	Dim	ensions (US m	smts.)		# Pieces:
Legend Device? State Control? ARCOS reportable? Co-Licensed?	Direct Ship Item	No No No No	Unit of Sale Bottle X Box/Carton Ampule	ORDER INFOR What is the M	RMATION IDC selling unit? e carton (Mono) . 1 Box of 10 Vials)	Yes	Box/ Carton:	Weight Lbs.	Dim Depth 2.16 Inches	Height 1.73 Inches	Width:		
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti	lic)	No No No No No No	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFOR What is the N One vial in on (Write-in, e.g	RMATION IDC selling unit? e carton (Mono) . 1 Box of 10 Vials) der quantity?	Yes	Box/	Weight Lbs.	Dim Depth	nensions (US m Height	width:		1 Vial
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	tic)	No N	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N One vial in on (Write-in, e.g	RMATION ADC selling unit? e carton (Mono) 1 Box of 10 Vials) der quantity? nany of which package	Yes	Box/ Carton:	Weight Lbs.	Dim Depth 2.16 Inches 12.20 Inches	Height 1.73 Inches	Width:		1 Vial 40 cartons
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti	tic)	No No No No No No	Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Powder Sql	ORDER INFORMATION ORDER INFORM	RMATION ADC selling unit? e carton (Mono) 1 Box of 10 Vials) Ader quantity? The package in t	Yes	Box/ Carton: Case:		Dim Depth 2.16 Inches	Height 1.73 Inches 10.82 Inches	width: 2.16 Inches 10.62 Inches		1 Vial 40 cartons (10x1)x4
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto	tic)	No N	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	ORDER INFOR What is the N One vial in on (Write-in, e.g	RMATION ADC selling unit? e carton (Mono) 1 Box of 10 Vials) Ader quantity? nany of which package Each Inner/Carton/Pack	Yes	Box/ Carton: Case:	Case:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches	1.73 Inches 10.82 Inches 40.67 Inches	width: 2.16 Inches 10.62 Inches		1 Vial 40 cartons (10x1)x4
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item	tic) ode: otoxic Agent?	No N	Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Powder Sql	ORDER INFORMATION ORDER INFORM	RMATION ADC selling unit? e carton (Mono) 1 Box of 10 Vials) Ader quantity? The package in t	Yes	Box/ Carton: Case: Pallet:		Dim Depth 2.16 Inches 12.20 Inches	1.73 Inches 10.82 Inches 40.67 Inches	width: 2.16 Inches 10.62 Inches		1 Vial 40 cartons (10x1)x4
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcott Controlled Substance Cottazardous Material/Cyto Is Item If Unit Dose, is item bar co	tic) ode: otoxic Agent?	No N	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In	ORDER INFOR What is the N One vial in on (Write-in, e.g Minimum ord If Yes, how n	RMATION IDC selling unit? e carton (Mono) .1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case:	Dim Depth 2.16 Inches 12.20 Inches 48 Inches	1.73 Inches 10.82 Inches 40.67 Inches	width: 2.16 Inches 10.62 Inches 40 Inches		1 Vial 40 cartons (10x1)x4
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	tic) ode: otoxic Agent?	No N	Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFOR What is the N One vial in on (Write-in, e.g Minimum ord If Yes, how n	RMATION IDC selling unit? e carton (Mono) .1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.16 Inches 12.20 Inches 48 Inches 35515022099	1.73 Inches 10.82 Inches 40.67 Inches	width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	1 Vial 40 cartons (10x1)x4 36 Shippers
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcott Controlled Substance Cottazardous Material/Cyto Is Item If Unit Dose, is item bar co	tic) ode: otoxic Agent?	No N	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In	ORDER INFOR What is the N One vial in on (Write-in, e.g Minimum ord If Yes, how n	RMATION IDC selling unit? e carton (Mono) .1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.16 Inches 12.20 Inches 48 Inches 35515022099	1.73 Inches 10.82 Inches 40.67 Inches	width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	1 Vial 40 cartons (10x1)x4
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoticontrolled Substance Compared Substance Sub	tic) ode: otoxic Agent? oded to unit dose for	No N	Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFOR What is the N One vial in on (Write-in, e.g Minimum ord If Yes, how n 40 / BILL UNIT	RMATION IDC selling unit? e carton (Mono) .1 Box of 10 Vials) Ider quantity? Inany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.16 Inches 12.20 Inches 48 Inches 35515022099	1.73 Inches 10.82 Inches 40.67 Inches	width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	1 Vial 40 cartons (10x1)x4 36 Shippers
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered?	tic) ode: otoxic Agent?	No N	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom	ORDER INFOR What is the N One vial in on (Write-in, e.g Minimum ord If Yes, how n 40 / BILL UNIT	RMATION ADC selling unit? e carton (Mono) 1 Box of 10 Vials) Ader quantity? Inany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr Product Shape:	Yes ge type? duct Information:	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.16 Inches 12.20 Inches 48 Inches 35515022099	1.73 Inches 10.82 Inches 40.67 Inches COST INFO	width: 2.16 Inches 10.62 Inches 40 Inches RMATION st (WAC) (\$)	(Cube)	1 Vial 40 cartons (10x1)x4 36 Shippers
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #:	tic) ode: otoxic Agent? oded to unit dose for	No N	Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g.	ORDER INFOR What is the N One vial in on (Write-in, e.g Minimum ord If Yes, how n 40 / BILL UNIT	RMATION IDC selling unit? e carton (Mono) .1 Box of 10 Vials) Ider quantity? Inany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	2.16 Inches 12.20 Inches 48 Inches 35515022099	1.73 Inches 10.82 Inches 40.67 Inches COST INFO	width: 2.16 Inches 10.62 Inches 40 Inches	(Cube)	1 Vial 40 cartons (10x1)x4 36 Shippers
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Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	otoxic Agent? oded to unit dose for	No N	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. Rx billing unit to pharm Each Gram Milliliter	ORDER INFOR What is the N One vial in on (Write-in, e.g Minimum ord If Yes, how n 40 / BILL UNIT ner? 1 Vial) nacy:	RMATION IDC selling unit? e carton (Mono) .1 Box of 10 Vials) Ider quantity? Inany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr Product Shape: Product Color: Product Imprint:	Yes ge type? duct Information: clear/colorless	Box/ Carton: Case: Pallet: UPC:	Case: Carton: Regular Cos Sale	2.16 Inches 12.20 Inches 48 Inches 35515022099	1.73 Inches 10.82 Inches 40.67 Inches Invoice Co.	2.16 Inches 10.62 Inches 40 Inches RMATION st (WAC) (\$)	(Cube)	1 Vial 40 cartons (10x1)x4 36 Shippers
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

M	ATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label	Hazardous Waste Identification							
c. Contact Hazard?								
d. Does this product require special clean-up instructions?	<u>) </u>							
(If yes, attach SDS with special instructions.)								
e. Does the product contain DEHP?	<u>, </u>							
Is this product regulated for shipment by the DOT?	o (if yes, answer a-d below and provide SDS) a. DOT Hazard Class							
Is this a reportable quantity?	b. UN/ID Number							
RQ Threshold:	c. Packing Group							
Is this a marine pollutant?	d. Inhalation Hazard?							
Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)								
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization							
Consumer Commodity, ORM-D	Level How? GTIN-14							
Small Quantity (49 CFR 173.4)	Serialized?							
Special Permit; DOT-SP	If not, when? Box/Carton 2D Linear RFID 00355150220991							
Special Provision (listed in Column 7 of 49 CFR 172.101);	Items aggregated to case? Case 2D Linear RFID 50355150220996							
SP#	Pallet 2D Linear RFID 70355150220990							
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS							
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:							
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)							
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer								
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS							
	Contact tel. # if product received damaged:							
	Is product returnable for credit:							
Listed Chemical (List I or II) (Indicate or Write-in below):	URL/Link to returns policy:							
Ephedrine	Special regulations or returns requirements for this product in certain states?							
Pseudoephedrine	If so, which states? Other requirements? Comments?							
Phenylpropanolamine								
lodine (≥2.2%)	<u> </u>							
Other:								
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:							
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:							
Restricted to hospital, clinics, and physician offices only:								
Restricted from US territories? (explain in comments)								
Comments:								
Comments:								
Comments:								
Comments:								



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 Fax Number: d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
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
	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:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Order receipt method: Phone: Phone #: Fax #:
Comments:	EDI:
	Overnight Fees apply: Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS: REMS Program Manager Name: Phone:	Contact # if product is received damaged:
Supplier Manages REMS registry exclusively:	Is product returnable for credit: URL/Link to returns policy:
Wholesale distributor support:	Special regulations or returns requirements for this product in certain states?
Provider Name:	If so, which states? Other requirements? Comments?
Site Enrollment Number assigned by Supplier: DEA #: PCPDP #: NPI #:	
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:	