

© August 2014			Int	troduction Type:	N	lew Item		Fi	nal Version		Date:		
		Р	RODUCT INFORMATION	ON					SPECIAL HAN	IDLING AND ST	TORAGE REQU	JIREMENTS*	
Company Name:	AuroMedics Pharma	II.C			Application:	AND	Α	a. Temperatur	e – Indicate th	ne USP tempera	ature range for	this product.	
Application Number fo			205612		дрисацоп.	71107	, ,		Freezer – hetw	een -25 and -10	) C (-13° – 14° F		
• •	or representations and a second	eu Device.	200012								,	,	
DUNS:		In		100.000/ 40/0/						n 2 and 8 C (36	,		
Rx Product/Proprietary N		Ropivacaine H	ydrochloride Injection, L							en 8 and 15 C (4		·	
NDC:	55150-195-20			UPC:	355150195206			x IV		oom – between 2		,	
CVX Code:				MVX Code:					allows for exc	cursions betweer	n 15 and 30 C (5	9° – 86° F)	
Description:	Ropivacaine Hydroch	nloride Injection, l	JSP 0.2% 40 mg/20 mL	L (2 mg/mL)				V.	. Avoid Excess	ive Heat – abov	e 40 C (>104° F	")	
		•						VI		rature Range Re	equirement		-
Active ingredients:								l —	(write in)				
								l L VI	II. No Requirem	nent			
URL for Additional Produ	uct Information:	www.auromedi	cs.com	<u></u>									
Address:	6 Wheeling Road			Address 2:				b. Contact for	temperature e	excursion ques	stions:		
City:	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas				
Key Contact:			Email:					Number:	732-823-4122	2			
Phone Number:	888-238-7880		Fax:	732-355-944	9			Is this produc	ct to be shipped	d to customers of	on ice?	No	_
		FOR (	GENERIC DRUG PRO	DUCTS				Is this produc	ct to be shipped	d to customers of	on dry ice?	No	
I. Orange Book Rating:	AP		II. Brand Name:	: Naropin				]					-
III. Generic Equivalent fo		ropivacaine	II. Diana Name.	. Ivaropin				c Special reg	ulations for n	oduct in certai	n etatos?	No	
III. Generic Equivalent 10								-	-				-
	DRU	IG SUPPLY CHA	IN SECURITY ACT (D	SCSA) INFORMAT	ION			Special retur	rns requiremen	ts for this produc	ct?	No	-
Does supplier meet DSC	SA definition of man	ufacturer?	Yes										
Is product exempt from I	DSCSA?	No						d. Store prod	uct (unit of sa	le) upriaht?		No	
If yes, select exemptio			<del>_</del>					•	•	sale) from light	2	No	-
Other exemption - Wri						1		Protect pro	duct (unit of s	sale) Irolli ligiti	f	INU	-
Other exemption - wil	ite iii.									_			
Is product repackaged?		No		ginal product pure	chased direct from m	nfr?		e. Shelf life:	24	Months			1
Is product sold by manu		distributor?	No	_		_		e. Shelf life:		Months fe at launch (if	different):		Months
		distributor? ode?	No No	If yes, attach	chased direct from mandation from	_		e. Shelf life:	Initial shelf li	fe at launch (if	•		Months
Is product sold by manu		distributor? ode?	No	If yes, attach		_		e. Shelf life:	Initial shelf li	1	•		Months
Is product sold by manu		distributor? ode?	No No	If yes, attach	documentation fron	_			Initial shelf li	fe at launch (if	ORMATION	Volume	
Is product sold by manu Are any waivers granted	l for product ID/barco	distributor? ode?	No No	If yes, attach	documentation fron	_		e. Shelf life: Weight Lbs.	Initial shelf li	fe at launch (if	ORMATION	Volume (Cube)	Months # Pieces:
Is product sold by manu Are any waivers granted Is the Product	l for product ID/barco	distributor? ode? ADDITIONAL F	No No PRODUCT INFORMAT	If yes, attach	documentation from	n FDA	ltem:		Initial shelf li ITEM AND	PACKING INFO	ORMATION smts.)		
Is product sold by manu Are any waivers granted Is the Product Legend Device?	l for product ID/barco	distributor? ode? ADDITIONAL F	No No PRODUCT INFORMAT  Unit of Sale	If yes, attach	RMATION NDC selling unit? te Carton. The Carton	n FDA	Item:		Initial shelf li ITEM AND	PACKING INFO	ORMATION smts.)		
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control?	l for product ID/barco	distributor? ode?  ADDITIONAL F	No No PRODUCT INFORMAT  Unit of Sale  Bottle	If yes, attach	RMATION NDC selling unit? te Carton. The Carton	n FDA	Box/	Weight Lbs.	Initial shelf li  ITEM AND  Dim  Depth	PACKING INFo ensions (US m Height	ORMATION smts.) Width:		# Pieces:
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	l for product ID/barco	distributor? dde?  ADDITIONAL F  No No No	No N	If yes, attachion  ORDER INFOI  What is the I  25 Vials in or 55150-195-2i  (Write-in, e.g.	RMATION NDC selling unit? te Carton. The Carton to 10 Vials)	n FDA			Initial shelf li ITEM AND	PACKING INFO	ORMATION smts.)		# Pieces:
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Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	distributor? ode?  ADDITIONAL F  No No No No	No N	If yes, attach  ORDER INFO  What is the I  25 Vials in or  55150-195-2i  (Write-in, e.g.	RMATION NDC selling unit? the Carton. The Carton to 1 Box of 10 Vials) der quantity?	NDC No. is	Box/	Weight Lbs.  2.34000 (Carton contains 25 12.307	Initial shelf li  ITEM AND  Dim  Depth	PACKING INFo ensions (US m Height	ORMATION smts.) Width:		# Pieces:  Vials) 2 Plyse (Two 3 Ply
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© August 2014			Intro	duction Type:	N	ew Item		'	Final Version		Date:		
		Р	RODUCT INFORMATION						SPECIAL HAN	NDLING AND S	TORAGE REQL	IREMENTS*	
Company Name:	AuroMedics Pharma	LLC			Application:	ANDA	Α	a. Temperatu	ıre – Indicate th	ne USP tempera	ature range for	this product.	
Application Number fo			205612		Application.	7,11427			Freezer – hetw	een -25 and -10	) C (-13° – 14° F		
• •	or representations and a second	ca Device.	2000.2								,	,	
DUNS:		In	1 11 11 11 11 11 11 11 11 11 11 11 11 1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	20 1 (0 / 1)				I. Cold – betwee	,	,		
Rx Product/Proprietary N		Ropivacaine H	ydrochloride Injection, USF						II. Cool – betwee	,	,	. <b>77</b> 0 E)	
NDC:	55150-196-99			UPC:	355150196999			x			20 and 25 C (68		
CVX Code:				MVX Code:					allows for exc	cursions betweei	n 15 and 30 C (5	9° – 86° F)	
Description:	Ropivacaine Hydroch	nloride Injection, l	JSP 0.2% 200 mg/100 mL	. (2 mg/mL)				\ \ \	<ul><li>V. Avoid Excess</li></ul>	ive Heat – abov	e 40 C (>104° F	)	
		1							I. Other Tempe	rature Range Re	equirement		,
Active ingredients:								<u> </u>	(write in)				]
								Ш '	/II. No Requiren	nent			
URL for Additional Produ	uct Information:	www.auromedi	cs.com										
Address:	6 Wheeling Road			Address 2:				b. Contact fo	r temperature	excursion ques	stions:		
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	9			Is this prod	uct to be shippe	d to customers of	on ice?	No	_
		FOR (	GENERIC DRUG PRODU	CTS				Is this prod	uct to be shippe	d to customers of	on dry ice?	No	
I. Orange Book Rating:	AP		II. Brand Name:	Naropin									-
III. Generic Equivalent fo		ropivacaine	II. Brana Name.	паторіп				c Special re	gulations for pi	roduct in certai	in states?	No	
III. Generic Equivalent 10		<u> </u>						-	-				-
	DRU	IG SUPPLY CHA	IN SECURITY ACT (DSC	SA) INFORMAT	ION			Special ret	urns requiremen	its for this produ	ct?	No	-
Does supplier meet DSC	SA definition of man	ufacturer?	Yes										
Is product exempt from I	DSCSA?	No						d. Store pro	duct (unit of sa	ile) upriaht?		No	
If yes, select exemptio			_						oduct (unit of	,	2	No	-
Other exemption - Wri						1		Protect pr	oduct (unit of s	sale) Iroin light	·f	INU	-
Other exemption - wil	ite III.					ļ				_			
Is product repackaged?		No	_	al product purc	hased direct from m	fr?		e. Shelf life:	24	Months			1
Is product sold by manu		distributor?	No			_		e. Shelf life:		Months ife at launch (if	different):		Months
		distributor?	No No	If yes, attach	chased direct from model	_		e. Shelf life:	Initial shelf li	ife at launch (if	•		Months
Is product sold by manu		distributor?	No	If yes, attach		_		e. Shelf life:	Initial shelf li	4	•		Months
Is product sold by manu		distributor?	No No	If yes, attach	documentation from	_			Initial shelf li	ife at launch (if	ORMATION	Volume	
Is product sold by manu Are any waivers granted	l for product ID/barco	distributor?	No No	If yes, attach	documentation from RMATION NDC selling unit?	n FDA		e. Shelf life: Weight Lbs	Initial shelf li	ife at launch (if	ORMATION	Volume (Cube)	Months # Pieces:
Is product sold by manu Are any waivers granted Is the Product	l for product ID/barco	distributor? ode? ADDITIONAL F	No No PRODUCT INFORMATION	If yes, attach  ORDER INFORMATIS the Mat is the Mat is one of the Mat is the Mat is one of the Mat is the Mat	RMATION NDC selling unit? Carton. The Carton ND	n FDA	ltem:		Initial shelf li ITEM AND	PACKING INF	ORMATION ismts.)		
Is product sold by manu Are any waivers granted Is the Product Legend Device?	l for product ID/barco	distributor? de?  ADDITIONAL F  No No No	No No No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton	order information of the state	RMATION NDC selling unit? Carton. The Carton NE	n FDA	Item:		Initial shelf li ITEM AND	PACKING INF	ORMATION ismts.)		
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	l for product ID/barco	distributor?  adde?  ADDITIONAL F  No  No  No  No	No No No PRODUCT INFORMATION  Unit of Sale  Bottle  x Box/Carton  Ampule	order information of the state	RMATION NDC selling unit? Carton. The Carton ND	n FDA	Box/	Weight Lbs	Initial shelf li  ITEM AND  Dim  Depth	PACKING INF DPACKING INF Densions (US m Height	ORMATION Ismts.) Width:		# Pieces:
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	l for product ID/barco	distributor? de?  ADDITIONAL F  No No No	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-98  (Write-in, e.g	RMATION NDC selling unit? Carton. The Carton ND 3 . 1 Box of 10 Vials)	n FDA			Initial shelf li ITEM AND	PACKING INF	ORMATION ismts.)		# Pieces:
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct Ship Item	distributor?  adde?  ADDITIONAL F  No  No  No  No	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-98  (Write-in, e.g	RMATION NDC selling unit? Carton. The Carton NE	n FDA	Box/ Carton:	Weight Lbs  U.49333 (Carton	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canonicontains 1	PACKING INF DEPACKING INF DEPA	ORMATION usmts.) Width:		# Pieces:  Vial) 2 Blysey
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	distributor?  adde?  ADDITIONAL F  No  No  No  No	No N	ORDER INFORMATION ORDER INFORM	RMATION NDC selling unit? Carton. The Carton ND 0 1. 1 Box of 10 Vials) der quantity?	DC No. is	Box/	Weight Lbs	Initial shelf li  ITEM AND  Dim  Depth	PACKING INF DPACKING INF Densions (US m Height	ORMATION Ismts.) Width:		# Pieces:  Canton (or Vial) 2 Pluse (Four 3 Ply
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	Direct Ship Item  Direct Ship Item	No N	No N	ORDER INFORMATION ORDER INFORM	RMATION NDC selling unit? Carton. The Carton ND 1. 1 Box of 10 Vials) der quantity? nany of which package	DC No. is	Box/ Carton:	Weight Lbs  U.49333 (Carton	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canonicontains 1	PACKING INF DEPACKING INF DEPA	ORMATION usmts.) Width:		# Pieces:  Vial) 2 Disser  (Four 3 Ply
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item  Direct Ship Item	distributor?  adde?  ADDITIONAL F  No  No  No  No	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-90 (Write-in, e.g.  Minimum ord  If Yes, how m	RMATION NDC selling unit? Carton. The Carton NE 3 1.1 Box of 10 Vials) der quantity? nany of which packar	DC No. is	Box/ Carton: Case:	0.49333 (Carton contains 1 22.604 840.770 (FO Sea)	Dim Depth  2.17 (Canon contains 1 Vial) 12.795	PACKING INF DPACKING INF Height  4.33 (Calton contains 1 Vial) 11.614 39.70 (FOI	ORMATION Usimts.) Width:  2.17 (canonicontains 25 Vials) 11.22		# Pieces:  Vial) 2 Ply Roy (Four 3 Ply
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	Direct Ship Item  Direct Ship Item	No N	No N	ORDER INFORMATION ORDER INFORM	RMATION NDC selling unit? Carton. The Carton NE 3 1. 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack	DC No. is	Box/ Carton: Case:	Weight Lbs  (Carton	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Caltori  contains 1  Viol)  12.795	PACKING INF Height	ORMATION Usimts.) Width:  2.17 (canonicontains 25 Vials) 11.22		# Pieces:  Vial) 2 Disser  (Four 3 Ply
Is product sold by manu Are any waivers granted  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	Direct Ship Item  Direct Ship Item  Licit Code: Direct Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-90 (Write-in, e.g.  Minimum ord  If Yes, how m	RMATION NDC selling unit? Carton. The Carton NE 3 1.1 Box of 10 Vials) der quantity? nany of which packar	DC No. is	Box/ Carton: Case: Pallet:	0.49333 (Carton contains 1 22.604 840.770 (FO Sea)	Dim Depth  2.17 (Canon contains 1 Vial) 12.795	PACKING INF Height	ORMATION Usimts.) Width:  2.17 (canonicontains 25 Vials) 11.22		# Pieces:  Vial) 2 Disser  (Four 3 Ply
Is product sold by manu Are any waivers granted  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  Direct Ship Item  Licit Code: Direct Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-90  (Write-in, e.g  Minimum ord  If Yes, how n  40	RMATION NDC selling unit? Carton. The Carton NE 3 1. 1 Box of 10 Vials) der quantity? nany of which packa Each Inner/Carton/Pack Case	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Caltori  contains 1  Viol)  12.795	PACKING INF Height	ORMATION ISIMES.) Width:  2.17 (Calton contains 25 Viale) 11.22 40		# Pieces:  Vial) 2 Disser  (Four 3 Ply
Is product sold by manu Are any waivers granted  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/Cyto Is Item If Unit Dose, is item bar cohospital scanning?	Direct Ship Item  Direct Ship Item  Licit Code: Direct Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-98  (Write-in, e.g  Minimum ord  If Yes, hown  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials) der quantity? nany of which packa Each Inner/Carton/Pack Case Other Proc	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604 640.770 (F0 Sea) 118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (canon  contains 1  Vial)  12.795  48  35515019699	PACKING INF Height	ORMATION ISIMES.) Width:  2.17 (Calton contains 25 Viale) 11.22 40	(Cube)	# Pieces:  Vial) 2 Blase (Four 3 Ply Pryor 38410 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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  Direct Ship Item  Licit Code: Direct Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-98  (Write-in, e.g  Minimum ord  If Yes, hown  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1. 1 Box of 10 Vials) der quantity? nany of which packa Each Inner/Carton/Pack Case	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canon  contains 1  12.795  48  35515019699	PACKING INF DEPACKING INF DEPA	ORMATION  Issmts.)  Width:  Contains 25  Viales  11.22  40  ORMATION	(Cube)	# Pieces:  Vial) 2 Pia Sev (Four 3 Ply Pryor Sed 10 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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/Cyto Is Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered?	Direct Ship Item  Direct Ship Item  Litic) ode: otoxic Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one of 55150-196-98  (Write-in, e.g  Minimum ord  If Yes, how n  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials) der quantity? nany of which packa Each Inner/Carton/Pack Case Other Proc	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (canon  contains 1  Vial)  12.795  48  35515019699	PACKING INF DEPACKING INF DEPA	ORMATION ISIMES.) Width:  2.17 (Calton contains 25 Viale) 11.22 40	(Cube)	# Pieces:  Vial) 2 Blase (Four 3 Ply Pryor 3241 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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/Cyto Is Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered?	Direct Ship Item  Direct Ship Item  Licit Code: Direct Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one of 55150-196-98  (Write-in, e.g  Minimum ord  If Yes, how n  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials) der quantity? nany of which packa Each Inner/Carton/Pack Case Other Proc	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canon  contains 1  12.795  48  35515019699	PACKING INF DEPACKING INF DEPA	ORMATION  Issmts.)  Width:  Contains 25  Viales  11.22  40  ORMATION	(Cube)	# Pieces:  Vial) 2 Pia Sev (Four 3 Ply Pryor Sed 10 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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  Direct Ship Item  Litic) ode: otoxic Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-90  (Write-in, e.g  Minimum ord  If Yes, how n  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials) der quantity? many of which packate Each Inner/Carton/Pack Case  Other Proc Size/Strength/Forn Product Shape:	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canon  contains 1  12.795  48  35515019699	PACKING INF DEPACKING INF DEPA	ORMATION  Issmts.)  Width:  Contains 25  Viales  11.22  40  ORMATION	(Cube)	# Pieces:  Vial) 2 Pia Sev (Four 3 Ply Pryor Sed 10 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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?  WHOLES Vendor #:	Direct Ship Item  Direct Ship Item  Litic) ode: otoxic Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-90  (Write-in, e.g  Minimum ord  If Yes, how n  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials) der quantity? nany of which packa Each Inner/Carton/Pack Case  Other Proc Size/Strength/Form	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canon  contains 1  12.795  48  35515019699	PACKING INF DEPACKING INF DEPA	ORMATION Usints.) Width:  2.17 (Canton contains 25 Viole) 11.22 40  ORMATION St (WAC) (\$)	(Cube)	# Pieces:  Vial) 2 Pia Sev (Four 3 Ply Pryor Sed 10 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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  Direct Ship Item  Litic) ode: otoxic Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-90  (Write-in, e.g  Minimum ord  If Yes, how n  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials) der quantity? many of which packate Each Inner/Carton/Pack Case  Other Proc Size/Strength/Forn Product Shape:	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canon  contains 1  12.795  48  35515019699	PACKING INF DEPACKING INF DEPA	ORMATION Usints.) Width:  2.17 (Canton contains 25 Viole) 11.22 40  ORMATION St (WAC) (\$)	(Cube)	# Pieces:  Vial) 2 Piggar (Four 3 Ply Pryor sed 1 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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?  WHOLES  Vendor #: Whsl. Code #:	Direct Ship Item  Direct Ship Item  Litic) ode: otoxic Agent?	No N	No N	If yes, attach  ORDER INFOR  What is the N  1 Vial in one 0 55150-196-90  (Write-in, e.g  Minimum ord  If Yes, how n  40  / BILL UNIT	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials) der quantity? nany of which packa Each Inner/Carton/Pack Case  Other Proc Size/Strength/Form Product Shape: Product Color:	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118.022 (Fc Case: Carton:	Initial shelf li  ITEM AND  Dim  Depth  2.17 (Canon  contains 1  12.795  48  35515019699	PACKING INF DEPACKING INF DEPA	ORMATION Usints.) Width:  2.17 (Canton contains 25 Viole) 11.22 40  ORMATION St (WAC) (\$)	(Cube)	# Pieces:  Vial) 2 Pia Sev (Four 3 Ply Pryor Sed 10 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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?  WHOLES  Vendor #: Whsl. Code #:	Direct Ship Item  Direct Ship Item  Direct Ship Item  Direct Ship Item  State of the state of th	No N	No N	If yes, attach  ORDER INFOR  What is the Market in the Mar	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials)  der quantity? nany of which packate Each Inner/Carton/Pack Case  Other Proc Size/Strength/Forn  Product Shape: Product Color: Product Imprint:	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118 022 (Ec Case: Carton:  Regular Co	Initial shelf li  ITEM AND Dim Depth  2.17 (Carton contains 1 Vial) 12.795  48 35515019699  ast Per Unit of le (\$)	PACKING INF Densions (US m Height  4.33 (Carton contains 1 11.614 39.70 (For Sea) 51.38 (For Air) 29  COST INFO Invoice Co  \$40  As of date:	ORMATION Isimts.) Width:	(Cube)	# Pieces:  Vial) 2 Pia Sev (Four 3 Ply Pryor Sed 10 (36 Shippers or 144 No's
Is product sold by manu Are any waivers granted  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?  WHOLES Vendor #: Whsl. Code #:	Direct Ship Item  Direct Ship Item  Direct Ship Item  Direct Ship Item  State of the state of th	No N	No N	If yes, attach  ORDER INFOR  What is the Market in the Mar	RMATION NDC selling unit? Carton. The Carton NE 3 1 Box of 10 Vials)  der quantity? nany of which packate Each Inner/Carton/Pack Case  Other Proc Size/Strength/Forn  Product Shape: Product Color: Product Imprint:	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	Weight Lbs  (Carton contains 1 22.604  640.770 (F0 Sea) 1118 022 (Ec Case: Carton:  Regular Co	Initial shelf li  ITEM AND Dim Depth  2.17 (Carton contains 1 Vial) 12.795  48 35515019699  ast Per Unit of le (\$)	PACKING INF Densions (US m Height  4.33 (Carton contains 1 11.614 39.70 (For Sea) 51.38 (For Air) 29  COST INFO Invoice Co  \$40  As of date:	ORMATION Isimts.) Width:	(Cube)	# Pieces:  Vial) 2 Pia Sev (Four 3 Ply Pryor Sed 10 (36 Shippers or 144 No's



			1111100	luction Type:	ine	w Item			Final Version		Date:		
		Р	RODUCT INFORMATION						SPECIAL HAN	IDLING AND ST	TORAGE REQU	IREMENTS*	
Company Name:	AuroMedics Pharma I	I.C			Application:	ANDA		a. Temperati	ıre – Indicate th	ne USP tempera	ature range for	this product.	
Application Number for			205612		Application.	ANDA	`		. Freezer – betw	•	ū	•	
	INDA/ANDA/BEA, INC	d Device.	200012								,	,	
DUNS:		In	1 11 11 11 11 11 11 11 11 11 11 11 11 1	0.50/ 100 /0	0 1 (5 ( 1)				I. Cold – betwee	,	,		
Rx Product/Proprietary Na		Ropivacaine H	ydrochloride Injection, USP						II. Cool – betwee	,	,		
	55150-197-20			UPC:	355150197200			х	V. Controlled Ro			,	
CVX Code:				MVX Code:					allows for exc	cursions betweer	1 15 and 30 C (5	9° – 86° F)	
Description:	Ropivacaine Hydroch	loride Injection, l	JSP 0.5% 100 mg/20 mL (	5 mg/mL)					<ul><li>V. Avoid Excess</li></ul>			)	
									I. Other Tempe	rature Range Re	equirement		
Active ingredients:									(write in)				
UBL C. ALIV IB I	. 1 . 6								/II. No Requiren	nent			
URL for Additional Produc		www.auromedi	cs.com										
	6 Wheeling Road			Address 2:				b. Contact fo	or temperature	excursion ques	stions:		
· ·	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas				
Key Contact:			Email:						: 732-823-4122				
Phone Number:	388-238-7880		Fax:	732-355-9449	)			Is this prod	uct to be shippe	d to customers of	on ice?	No	
		FOR (	GENERIC DRUG PRODU	CTS				Is this prod	uct to be shippe	d to customers of	on dry ice?	No	
I. Orange Book Rating:	<b>\</b> P		II. Brand Name:	Naropin									
III. Generic Equivalent for I		ropivacaine						c. Special re	gulations for pi	oduct in certai	n states?	No	
			IN SECURITY ACT (DSC	SA) INFORMAT	ION		· ·	-	urns requiremen			No	
			•	SA) INI OKWAT	ION			Special ret	ums requiremen	is for this produc	JI!	INU	
Does supplier meet DSCS	A definition of manu	ıfacturer?	Yes										
Is product exempt from DS	SCSA?	No	_					d. Store pro	duct (unit of sa	le) upright?		No	
If yes, select exemption:	:							Protect p	oduct (unit of	sale) from light	?	No	
Other exemption - Write										3			
ls product repackaged?		No	If Voc. was origin:	al product pure	hased direct from mf	r2		e. Shelf life:	24	Months			
Is product repackaged:	cturer's exclusive d		No	ai product purc	naseu unect nom mi	''		e. Sileli ille.		fe at launch (if	different):		Months
Are any waivers granted for			No	If ves. attach	documentation from	FDA			initial one ii	io at iaarion (ii	amorom,		montais
, , , , , , , , ,			PRODUCT INFORMATION	• •					ITEM AND	PACKING INF	ORMATION		
		ADDITIONAL	RODUCT IN ORMATION										
_	Direct Ship Item								Dim	ensions (US m	smts.)	Volume	
Legend Device?				ORDER INFOR				Weight Lbs				(0.1.)	# Pieces:
•		No	Unit of Sale	What is the N	IDC selling unit?	IDC No. is		Weight Lbs	. Depth	Height	Width:	(Cube)	# Pieces:
State Control?		No	Bottle	What is the N 25 Vials in on	IDC selling unit? e Carton. The Carton N	IDC No. is	Item:	Weight Lbs	Depth	Height	Width:	(Cube)	# Pieces:
State Control? ARCOS reportable?		No No	Bottle x Box/Carton	What is the N 25 Vials in on 55150-197-20	NDC selling unit? e Carton. The Carton N	IDC No. is		Weight Lbs	Depth	Height	Width:	(Cube)	# Pieces:
State Control? ARCOS reportable? Co-Licensed?		No No No	Bottle x Box/Carton Ampule	What is the N 25 Vials in on 55150-197-20	IDC selling unit? e Carton. The Carton N	IDC No. is	Box/	Z.34030 (Carton	Depth  O.77 (Carton contains 25	Height  2.03(Carton contains 25	Width:	(Cube)	Canon (23 Vials)
State Control? ARCOS reportable? Co-Licensed? Controlled Substance?		No No	Bottle x Box/Carton Ampule Glass	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g	ADC selling unit? e Carton. The Carton N ) . 1 Box of 10 Vials)		Box/ Carton:	(Carton	contains 25	contains 25	contains 25	(Cube)	Vials)
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?		No No No	Bottle x Box/Carton Ampule Glass Tube	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g	NDC selling unit? e Carton. The Carton N	IDC No. is	Box/	2.54050	Depth	2.03(Canton	o.rr (Canton	(Cube)	Vials)  2 Plaser  (Two 3 Ply
State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	•	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl	What is the N 25 Vials in on 55150-197-20 (Write-in, e.g	IDC selling unit? e Carton. The Carton N ) . 1 Box of 10 Vials) der quantity?	Yes	Box/ Carton: Case:	2.34030 (Carton contains 25 12.307	contains 25	2.05(Carton contains 25 Viole) 8.661 39.57 (FO	contains 25	(Cube)	Vials)  2 Plase  (Two 3 Ply  Pronser4
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Cod	le:	No No No	Bottle x Box/Carton Ampule Glass Tube	What is the N 25 Vials in on 55150-197-20 (Write-in, e.g	ADC selling unit? e Carton. The Carton N ) . 1 Box of 10 Vials)	Yes	Box/ Carton:	(Carton contains 25	contains 25	contains 25	contains 25	(Cube)	Vials)  2 Clases  (Two 3 Ply  Prorsea  (60 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic)	le:	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	What is the N 25 Vials in on 55150-197-20 (Write-in, e.g	IDC selling unit? e Carton. The Carton N ) .1 Box of 10 Vials) der quantity?	Yes	Box/ Carton: Case: Pallet:	2.34030 (Carton contains 25 12.307	contains 25	2.05(Carton contains 25 Viole) 8.661 59.37 (FUI Sea)	contains 25	(Cube)	Vials)  2 Plase  (Two 3 Ply  Pronser4
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Cod	le:	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum ord  If Yes, how n	IDC selling unit? e Carton. The Carton N ) . 1 Box of 10 Vials)  der quantity?  nany of which packag  Each	Yes	Box/ Carton: Case:	(Carton	contains 25	2.05(Carton contains 25 Viole) 8.661 39.37 (FOI Sea) 56.89 (For Air)	contains 25	(Cube)	Vials)  2 Clases  (Two 3 Ply  Prorsea  (60 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto	le: oxic Agent?	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum ord  If Yes, how n	IDC selling unit? e Carton. The Carton N  1. 1 Box of 10 Vials)  Ider quantity?  anny of which packag  Each  Inner/Carton/Pack	Yes	Box/ Carton: Case: Pallet:	(Carton contains 25 12.307 771.430 (FG Sea) 1140.664 (EG	contains 25 Viale) 15.157	2.05(Carton contains 25 Viole) 8.661 39.37 (FOI Sea) 56.89 (For Air)	contains 25	(Cube)	Vials)  2 Clases  (Two 3 Ply  Prorsea  (60 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto	le: oxic Agent?	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n	IDC selling unit? e Carton. The Carton N  1. 1 Box of 10 Vials)  Ider quantity?  anny of which packag  Each  Inner/Carton/Pack  Case	Yes	Box/ Carton: Case: Pallet: UPC:	(Carton contains 25 12.307 771.430 (FG Sea) 1140.664 (EG	contains 25 Viale) 15.157	2.00(Carton contains 25 Viole) 8.661 39.37 (For Sea) 56.89 (For Air)	contains 25 Violes 8.071 40	(Cube)	Vials)  2 Clases  (Two 3 Ply  Prorsea  (60 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code	le: oxic Agent?	No No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4	IDC selling unit? e Carton. The Carton N  1. 1 Box of 10 Vials)  Ider quantity?  anny of which packag Each Inner/Carton/Pack Case  Other Produ	Yes je type?	Box/ Carton: Case: Pallet: UPC:	2.34000 (Carton 	Depth  0.77 (Calton contains 25 Viale) 15.157  48 35515019720	2.00(Carton contains 25 Viale) 8.661 8.661 Sea) 56.89 (For Air)	contains 25 Viale  8.071  40		Vials)  2 Clases  (Two 3 Ply  Prorsea  (60 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning?	le: oxic Agent?	No No No No	Bottle  x Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sql  Vial Power Multi  Other: Write In  PHARMACY ORDER	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4	IDC selling unit? e Carton. The Carton N  1. 1 Box of 10 Vials)  Ider quantity?  anny of which packag  Each  Inner/Carton/Pack  Case	Yes je type?	Box/ Carton: Case: Pallet: UPC:	(Carton contains 26 12.307 771.400 (Fo Sea) 1140.664 /Ec Case: Carton:	contains 25 Viale) 15.157	2.00(Carton contains 25 Viale) 8.661 8.661 Sea) 56.89 (For Air)	contains 25 Violes 8.071 40	Federal Exc	Vials) 2 Pluse (Two 3 Ply Pronses (60 Shippers or 120 No's
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning? Is it reverse numbered?	le: oxic Agent? ed to unit dose for	No No No No	Bottle  x Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sql  Vial Power Multi  Other: Write In  PHARMACY ORDER	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum ord  If Yes, how n  4  BILL UNIT	e Carton. The Carton N  1. 1 Box of 10 Vials)  der quantity?  nany of which packag Each Inner/Carton/Pack Case  Other Prod Size/Strength/Form	Yes je type?	Box/ Carton: Case: Pallet: UPC:	(Carton contains 26 12.307 771.400 (Fo Sea) 1140.664 /Ec Case: Carton:	Depth  0.77 (Caltorn contains 25 Viale) 15.157  48 35515019720	2.00(Carton contains 25 Viale) 8.661 8.661 Sea) 56.89 (For Air)	contains 25 Viale  8.071  40	Federal Exc	Vials) 2 Blase (Two 3 Ply Promses (60 Shippers or 120 No's
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning? Is it reverse numbered?	le: oxic Agent?	No No No No	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 custon (Write-in, e.g. 1	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4  BILL UNIT ner?  Vial)	e Carton. The Carton N  1 Box of 10 Vials)  der quantity?  nany of which packag Each Inner/Carton/Pack Case  Other Prod  Size/Strength/Form  Product Shape:	Yes je type?	Box/ Carton: Case: Pallet: UPC:	(Carton contains 26 12.307 771.400 (Fo Sea) 1140.664 /Ec Case: Carton:	Depth  0.77 (Caltorn contains 25 Viale) 15.157  48 35515019720	2.00(Carton contains 25  Viole)  8.661  Sea)  56.80 (For Air)  COST INFO  Invoice Cost	8.071 40 RMATION st (WAC) (\$)	Federal Exc	Vials) 2 Blase (Two 3 Ply Promses (60 Shippers or 120 No's
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning? Is it reverse numbered?  WHOLESA Vendor #:	le: oxic Agent? ed to unit dose for	No No No No	Bottle  x Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Powder Sql  Vial Power Multi  Other: Write In  PHARMACY ORDER  Rec. sell unit to custon  (Write-in, e.g. 1	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4  BILL UNIT ner?  Vial)	e Carton. The Carton N  1. 1 Box of 10 Vials)  der quantity?  nany of which packag Each Inner/Carton/Pack Case  Other Prod Size/Strength/Form	Yes je type?	Box/ Carton: Case: Pallet: UPC:	(Carton contains 26 12.307 771.400 (Fo Sea) 1140.664 /Ec Case: Carton:	Depth  0.77 (Caltorn contains 25 Viale) 15.157  48 35515019720	2.00(Carton contains 25  Viole)  8.661  Sea)  56.80 (For Air)  COST INFO  Invoice Cost	contains 25 Viale  8.071  40	Federal Exc	Vials) 2 Blase (Two 3 Ply Promses (60 Shippers or 120 No's
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning? Is it reverse numbered?  WHOLESA Vendor #: Whsl. Code #:	le: oxic Agent? ed to unit dose for	No No No No	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 custon  (Write-in, e.g. 1  Rx billing unit to pharm Each	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4  BILL UNIT ner?  Vial)	IDC selling unit? e Carton. The Carton N  1. 1 Box of 10 Vials)  Ider quantity?  Inany of which packag Each Inner/Carton/Pack Case  Other Prod Size/Strength/Form  Product Shape: Product Color:	Yes je type?	Box/ Carton: Case: Pallet: UPC:	(Carton contains 26 12.307 771.400 (Fo Sea) 1140.664 /Ec Case: Carton:	Depth  0.77 (Caltorn contains 25 Viale) 15.157  48 35515019720	2.00(Carton contains 25  Viole)  8.661  Sea)  56.80 (For Air)  COST INFO  Invoice Cost	8.071 40 RMATION st (WAC) (\$)	Federal Exc	Vials) 2 Blase (Two 3 Ply Promses (60 Shippers or 120 No's
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning? Is it reverse numbered?  WHOLESA Vendor #:	le: oxic Agent? ed to unit dose for	No No No No	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 custon (Write-in, e.g. 1  Rx billing unit to pharm Each Gram	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4  BILL UNIT ner?  Vial)	e Carton. The Carton N  1 Box of 10 Vials)  der quantity?  nany of which packag Each Inner/Carton/Pack Case  Other Prod  Size/Strength/Form  Product Shape:	Yes je type?	Box/ Carton: Case: Pallet: UPC:	(Carton contains 26 12.307 771.400 (Fo Sea) 1140.664 /Ec Case: Carton:	Depth  0.77 (Caltorn contains 25 Viale) 15.157  48 35515019720	2.03 (Carton contains 25 Viole) 8.661 Sea) 56.89 (For Air) 00  COST INFO Invoice Cos	0.77 (Carton contains 25 Viole) 8.071 40 RMATION st (WAC) (\$)	Federal Exc	Vials) 2 Blase (Two 3 Ply Promses (60 Shippers or 120 No's
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning? Is it reverse numbered?  WHOLESA Vendor #: Whsl. Code #:	ed to unit dose for	No No No No	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 custon  (Write-in, e.g. 1  Rx billing unit to pharm Each Gram Milliliter	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4  /BILL UNIT her?  Vial) hacy:	IDC selling unit? e Carton. The Carton N  1. 1 Box of 10 Vials)  Ider quantity?  Inany of which packag Each Inner/Carton/Pack Case  Other Prod  Size/Strength/Form  Product Shape: Product Color:  Product Imprint:	Yes je type?  uct Informatio	Box/ Carton: Case: Pallet: UPC:	(Carton Carton 25 12.307 771.430 (FG Sea) 1140.664 (Fc Case: Carton: Sa	Depth  0.77 (Caltorn contains 25 Viale) 15.157  48 35515019720  set Per Unit of le (\$)	2.00(Carton contains 25 Viale) 8.661 Sea) 56.80 (For Air) 00  COST INFO Invoice Cost \$35	8.071 40 RMATION st (WAC) (\$)	Federal Exc	Vials) 2 Blase (Two 3 Ply Promses (60 Shippers or 120 No's
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic; Controlled Substance Cod Hazardous Material/Cytoto Is Item If Unit Dose, is item bar code hospital scanning? Is it reverse numbered?  WHOLESA Vendor #: Whsl. Code #:	ed to unit dose for	No No No No	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 custon (Write-in, e.g. 1  Rx billing unit to pharm Each Gram	What is the M 25 Vials in on 55150-197-20 (Write-in, e.g  Minimum orc  If Yes, how n 4  /BILL UNIT her?  Vial) hacy:	IDC selling unit? e Carton. The Carton N  1. 1 Box of 10 Vials)  Ider quantity?  Inany of which packag Each Inner/Carton/Pack Case  Other Prod  Size/Strength/Form  Product Shape: Product Color:  Product Imprint:	Yes je type?  uct Informatio	Box/ Carton: Case: Pallet: UPC:	(Carton Carton 25 12.307 771.430 (FG Sea) 1140.664 (Fc Case: Carton: Sa	Depth  0.77 (Caltorn contains 25 Viale) 15.157  48 35515019720  set Per Unit of le (\$)	2.00(Carton contains 25 Viale) 8.661 Sea) 56.80 (For Air) 00  COST INFO Invoice Cost \$35	0.77 (Carton contains 25 Viole) 8.071 40 RMATION st (WAC) (\$)	Federal Exc	Vials) 2 Blase (Two 3 Ply Promses (60 Shippers or 120 No's



© August 2014			In	troduction Type:	N	lew Item		F	inal Version		Date:		
		Р	RODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND S	TORAGE REQU	IREMENTS*	
Company Name:	AuroMedics Pharma	LLC			Application:	AND	Δ	a. Temperatu	re – Indicate th	ne USP tempera	ature range for	this product.	
Application Number fo			205612		Аррисацоп.	AND		l <u>-</u>		een -25 and -10	•	•	
• •	OI NOA/ANDA/DEA, III	ica Device.	200012	_							,	,	
DUNS:		ls · · · ·		1100 0 50/ 450 //	20 1 (5 ( 1 )					en 2 and 8 C (36	,		
Rx Product/Proprietary N		Ropivacaine H	ydrochloride Injection,							en 8 and 15 C (4			
NDC:	55150-198-30			UPC:	355150198306			<u>x</u> 1\		oom – between 2	•	,	
CVX Code:				MVX Code:					allows for exc	cursions between	1 15 and 30 C (5	9° – 86° F)	
Description:	Ropivacaine Hydroch	hloride Injection, l	JSP 0.5% 150 mg/30 r	mL (5 mg/mL)						ive Heat – abov		)	
								v		rature Range Re	equirement		7
Active ingredients:								l — ,,	(write in)	L			]
LIDI for Additional Decid		www.auromedi						L v	II. No Requirem	nent			
URL for Additional Produ		www.auromedi	CS.COM	_									
Address:	6 Wheeling Road			Address 2:		_				excursion ques	stions:		
City:	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas				
Key Contact:			Email:						732-823-4122				
Phone Number:	888-238-7880		Fax:	732-355-944	9			-		d to customers of		No	_
		FOR (	GENERIC DRUG PRO	DUCTS				Is this produ	ict to be shipped	d to customers of	on dry ice?	No	_
I. Orange Book Rating:	AP		II. Brand Name	: Naropin									
III. Generic Equivalent fo	or Brand:	ropivacaine						c. Special reg	ulations for pr	roduct in certai	n states?	No	
•	DRII	IG SLIPPLY CHA	IN SECURITY ACT (D	SCSA) INFORMAT	ION				-	ts for this produc		No	-
- "			· ·	OCCA) IN CRIMA	1011			Special retu	ins requiremen	is for this produc	J.:	INO	-
Does supplier meet DSC	SA definition of man	iufacturer?	Yes	_									
Is product exempt from I	DSCSA?	No	_					d. Store prod	luct (unit of sa	le) upright?		No	_
If yes, select exemptio	on:							Protect pro	oduct (unit of s	sale) from light	?	No	
Other exemption - Wri	ite in:							_	•	,			-
						-				7			
Is product repackaged?		No	If Yes was ori	iginal product pure	chased direct from m	fr?		e Shelf life:	24	Months			
Is product repackaged?	facturer's exclusive	No distributor?		iginal product purd	chased direct from m	nfr?		e. Shelf life:	24 Initial shelf li	Months	different):		Months
Is product sold by manu		distributor?	If Yes, was ori No No	_	chased direct from m	_		e. Shelf life:		Months ife at launch (if	different):		Months
		distributor? ode?	No No	If yes, attach		_		e. Shelf life:	Initial shelf li	ife at launch (if	•		Months
Is product sold by manu Are any waivers granted	l for product ID/barco	distributor? ode?	No	If yes, attach	n documentation from	_		e. Shelf life:	Initial shelf li	fe at launch (if	ORMATION		Months
Is product sold by manu Are any waivers granted Is the Product		distributor? ode? ADDITIONAL F	No No PRODUCT INFORMAT	If yes, attach	n documentation from	_		e. Shelf life: Weight Lbs.	Initial shelf li ITEM AND	PACKING INF	ORMATION smts.)	Volume	Months # Pieces:
Is product sold by manu Are any waivers granted Is the Product Legend Device?	l for product ID/barco	distributor? ode? ADDITIONAL F	No No PRODUCT INFORMAT	If yes, attach	n documentation from RMATION NDC selling unit?	n FDA			Initial shelf li	fe at launch (if	ORMATION	Volume (Cube)	
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control?	l for product ID/barco	distributor? ode?  ADDITIONAL F	No No PRODUCT INFORMAT  Unit of Sale Bottle	If yes, attach TION  ORDER INFO  What is the I  25 Vials in or	n documentation from RMATION NDC selling unit? ne Carton. The Carton	n FDA	Item:		Initial shelf li ITEM AND	PACKING INF	ORMATION smts.)		
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable?	l for product ID/barco	distributor?  ode?  ADDITIONAL F  No No No	No No No PRODUCT INFORMAT Unit of Sale Bottle x Box/Carton	If yes, attach FION  ORDER INFO  What is the I  25 Vials in or 55150-198-30	RMATION NDC selling unit? the Carton. The Carton	n FDA		Weight Lbs.	Initial shelf li  ITEM AND  Dim  Depth	PACKING INFormation (IS mensions (US mensions)	ORMATION smts.) Width:		# Pieces:
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	l for product ID/barco	distributor? ode?  ADDITIONAL F  No No No No	No No No PRODUCT INFORMAT  Unit of Sale  Bottle  x Box/Carton  Ampule	If yes, attach FION  ORDER INFO  What is the I  25 Vials in or 55150-198-30	n documentation from RMATION NDC selling unit? ne Carton. The Carton	n FDA	Box/		Initial shelf li ITEM AND	PACKING INF	ORMATION smts.)		# Pieces:
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	l for product ID/barco	distributor?  ode?  ADDITIONAL F  No No No	No N	If yes, attach  ORDER INFOI  What is the I  25 Vials in or 55150-198-30  (Write-in, e.g.	RMATION NDC selling unit? the Carton. The Carton 0 1. 1 Box of 10 Vials)	n FDA  NDC No. is	Box/ Carton:	Weight Lbs.	Initial shelf li  ITEM AND  Dim  Depth  O.77 (Callonicontains 25)  Viale)	PACKING INF- ensions (US m Height	ormation smts.) Width:  contains 25		# Pieces:  Vals) 2 Bluser
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	Direct Ship Item	distributor? ode?  ADDITIONAL F  No No No No	No No No PRODUCT INFORMAT  Unit of Sale  Bottle  x Box/Carton  Ampule	If yes, attach  ORDER INFOI  What is the I  25 Vials in or 55150-198-30  (Write-in, e.g.	RMATION NDC selling unit? the Carton. The Carton	n FDA	Box/	Weight Lbs.  3.47010 (Carton contains 25 16.104	Initial shelf li  ITEM AND  Dim  Depth	PACKING INFormation (IS mensions (US mensions)	ORMATION smts.) Width:		# Pieces:  Vials) 2 Ply Sev (Two 3 Ply
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct Ship Item	distributor? ode?  ADDITIONAL F  No No No No	No No No PRODUCT INFORMAT  Unit of Sale Bottle x Box/Carton Ampule Glass Tube	If yes, attach  ORDER INFO  What is the I  25 Vials in or  55150-198-30  (Write-in, e.g.  Minimum ord	RMATION NDC selling unit? the Carton. The Carton 0 1. 1 Box of 10 Vials)	NDC No. is	Box/ Carton: Case:	Weight Lbs.  (Carton Contains 25 16.104	Initial shelf li  ITEM AND  Dim  Depth  Contains 25  Viole  15.157	PACKING INF  PACKING INF  Lensions (US m  Height  J.23 (Carton  contains 25  Viole)  9.449  42.72 (FOI	ORMATION smts.) Width:  U.17 (Canton contains 25 Viole)  8.071		# Pieces:  Vials) 2 Busev (Two 3 Ply Pronse4
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item  Direct Ship Item	distributor? ode?  ADDITIONAL F  No No No No	Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl	If yes, attach  ORDER INFO  What is the I  25 Vials in on 55150-198-3  (Write-in, e.c.  Minimum ord  If Yes, how r	RMATION NDC selling unit? the Carton. The Carton 0 g. 1 Box of 10 Vials) der quantity?	NDC No. is	Box/ Carton:	Weight Lbs.  3.47010 (Carton contains 25 16.104	Initial shelf li  ITEM AND  Dim  Depth  O.77 (Callonicontains 25)  Viale)	PACKING INF DEPACKING INF DEPA	ormation smts.) Width:  contains 25		# Pieces:  Vials) 2 Ply Sev (Two 3 Ply
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© August 2014			Int	roduction Type:	N	New Item		Fir	nal Version		Date:		
		P	RODUCT INFORMATION	ON				,	SPECIAL HAN	IDLING AND ST	TORAGE REQU	IREMENTS*	
Company Name:	AuroMedics Pharma	LLC			Application:	AND	Ą	a. Temperature	e – Indicate th	e USP tempera	ature range for	this product.	
Application Number for			205612		. фр.:са.:с.::			l l. F	reezer – betw	een -25 and -10	C (-13° – 14° F	)	
DUNS:	,		l e							n 2 and 8 C (36	,	,	
Rx Product/Proprietary N	lame.	Ropivacaine Hy	vdrochloride Injection, U	ISP 0.75% 150 mg/	/20 ml (7.5 mg/ml)			l —		en 8 and 15 C (4	,		
	55150-199-20	r topi v dodanio i i	, ar corneriae injection, e	UPC:	355150199204			l ——		,	20 and 25 C (68	° – 77° F)	
CVX Code:				MVX Code:							n 15 and 30 C (5		
Description:	Ponivacaine Hydroch	loride Injection I	JSP 0.75% 150 mg/20 i								e 40 C (>104° F		
Description.	Ropivacame riyuroch	nonde injection, e	701 0.7570 130 mg/20 i	ne (7.5 mg/me)				l —		rature Range Re	•	,	
Active ingredients:									(write in)	g			1
•								VII	I. No Requirem	ent			_
URL for Additional Produ	ct Information:	www.auromedi	cs.com										
Address:	6 Wheeling Road			Address 2:				b. Contact for	temperature e	excursion ques	stions:		
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	9			Is this produc	t to be shipped	d to customers of	on ice?	No	<u>.</u>
		FOR (	GENERIC DRUG PRO	DUCTS				Is this produc	ct to be shipped	d to customers o	on dry ice?	No	
I. Orange Book Rating:	AP		II. Brand Name:	Naropin									<u>-</u>
III. Generic Equivalent for		ropivacaine						c. Special regu	ulations for pr	oduct in certai	n states?	No	
	DRU	G SUPPLY CHA	IN SECURITY ACT (D	SCSA) INFORMAT	ION			Special return	ns requirement	ts for this produc	~t?	No	=
Does supplier meet DSCS			Yes	, , , , , , , , , , , , , , , , , , , ,				opeoidi retaii	no requirement	io for tino produc	J	110	-
• •			res	_				_					
Is product exempt from D	OSCSA?	No	_					d. Store produ	uct (unit of sa	le) upright?		No	=
If yes, select exemption								Protect prod	duct (unit of s	ale) from light	?	No	_
Other exemption - Writ	e in:									_			
Is product repackaged?		No	If Yes, was oriç	inal product purc	hased direct from m	nfr?		e. Shelf life:	24	Months			-
Is product sold by manuf		listributor?	No	<u> </u>						Months fe at launch (if	different):		Months
		listributor? de?	No No	If yes, attach	chased direct from mandation from				Initial shelf li	fe at launch (if	•		Months
Is product sold by manuf		listributor? de?	No	If yes, attach					Initial shelf li	L.	•		Months
Is product sold by manuf Are any waivers granted		listributor? de?	No No	If yes, attach	documentation fror				Initial shelf life	fe at launch (if	ORMATION	Volume	
Is product sold by manuf Are any waivers granted	for product ID/barco	listributor? de?	No No	If yes, attach	documentation from	m FDA			Initial shelf life	fe at launch (if	ORMATION	Volume (Cube)	Months  # Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barco	de?  ADDITIONAL F  No No	No No No PRODUCT INFORMATION Unit of Sale Bottle	If yes, attach ON ORDER INFOR What is the N 25 Vials in on	RMATION NDC selling unit? e Carton. The Carton	m FDA	Item:		Initial shelf lif	fe at launch (if  PACKING INFO	ORMATION smts.)		
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barco	de? ADDITIONAL F  No No No	No N	on or	RMATION NDC selling unit? e Carton. The Carton	m FDA	Item:	Weight Lbs.	Initial shelf lif	PACKING INFo ensions (US m Height	ORMATION smts.) Width:		# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	for product ID/barco	de?  ADDITIONAL F  NO NO NO NO	No N	on or	RMATION NDC selling unit? e Carton. The Carton	m FDA	Box/		Initial shelf lif	fe at launch (if  PACKING INFO	ORMATION smts.)		
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© August 2014			lr	ntroduction Type:	N	lew Item		Fi	nal Version		Date:		
		Р	RODUCT INFORMAT	ION				:	SPECIAL HAN	IDLING AND ST	ORAGE REQU	IREMENTS*	
Company Name:	AuroMedics Pharma	II.C.			Application:	AND	Α	a. Temperatur	e – Indicate th	e USP tempera	ture range for	this product.	
Application Number fo			205612		дрисацоп.	71107	, ,		Freezer – hetw	een -25 and -10	C (-13° – 14° F	,	
• •	, NOTOTALOPADER, III	cu Device.	2000.2	_							,	,	
DUNS:		Danis anning 11	.do. abladala laia stian	LICD 40/ 400/40	) (40 ( L)			l —		n 2 and 8 C (36	,		
Rx Product/Proprietary N		Ropivacaine H	ydrochloride Injection,		_ `					en 8 and 15 C (4	,	, 770 F)	
NDC:	55150-200-10			UPC:	355150200108			x IV		om – between 2	•		
CVX Code:				MVX Code:					allows for exc	ursions betweer	15 and 30 C (5	19° – 86° F)	
Description:	Ropivacaine Hydroch	loride Injection, l	JSP 1% 100 mg/10 ml	L (10 mg/mL)				V.	Avoid Excessi	ve Heat – abov	e 40 C (>104° F	)	
								VI		rature Range Re	equirement		1
Active ingredients:									(write in)				
									I. No Requirem	ent			
URL for Additional Produ	uct Information:	www.auromedi	cs.com										
Address:	6 Wheeling Road			Address 2:				b. Contact for	temperature e	excursion ques	tions:		
City:	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas				
Key Contact:			Email:					Number:	732-823-4122	2			
Phone Number:	888-238-7880		Fax:	732-355-944	9			Is this produc	ct to be shipped	d to customers of	n ice?	No	_
		FOR (	GENERIC DRUG PRO	DUCTS				Is this produc	ct to be shipped	d to customers o	n dry ice?	No	
I. Orange Book Rating:	AP		II. Brand Name	: Naropin									-
III. Generic Equivalent fo		ropivacaine	II. Diana Name	. Naiopin				c Special regi	ulations for nr	oduct in certai	n states?	No	
III. Generic Equivalent 10					TO L			_	-				-
	DRU	G SUPPLY CHA	IN SECURITY ACT (	DSCSA) INFORMAT	IION			Special retur	ns requirement	ts for this produc	t?	No	-
Does supplier meet DSC	SA definition of man	ufacturer?	Yes										
Is product exempt from I	DSCSA?	No						d. Store prod	uct (unit of sa	le) upright?		No	
If yes, select exemptio	n.		<del>-</del>					Protect pro	duct (unit of s	ale) from light	2	No	='
Other exemption - Wri						1		1 Totect pro	duct (dillicor s	ale, nom ngm	•	140	-
outer oxomption in													
1 1		No	17.37					01 17 17	0.4				
Is product repackaged?		No No		iginal product pure	chased direct from m	nfr?		e. Shelf life:	24	Months	-l:ff()-		1
Is product sold by manu		distributor?	No	<u> </u>		_		e. Shelf life:		Months fe at launch (if	different):		Months
		distributor? de?	No No	If yes, attach	chased direct from m	_		e. Shelf life:	Initial shelf li	fe at launch (if	,		Months
Is product sold by manu		distributor? de?	No	If yes, attach	n documentation fror	_		e. Shelf life:	Initial shelf li	L.	,		Months
Is product sold by manu		distributor? de? ADDITIONAL F	No No PRODUCT INFORMAT	If yes, attach	n documentation from	_			Initial shelf li	fe at launch (if	ORMATION	Volume	
Is product sold by manu Are any waivers granted	for product ID/barco	distributor? de?	No No	If yes, attach	n documentation from RMATION NDC selling unit?	n FDA		e. Shelf life: Weight Lbs.	Initial shelf li	fe at launch (if	ORMATION	Volume (Cube)	Months # Pieces:
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control?	for product ID/barco	distributor? de? ADDITIONAL F	No No No PRODUCT INFORMATE Unit of Sale Bottle	If yes, attach FION ORDER INFO What is the I 25 Vials in or	n documentation from RMATION NDC selling unit? ne Carton. The Carton	n FDA	Item:		Initial shelf li	Fe at launch (if  PACKING INFO	ORMATION smts.)		
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barco	de? ADDITIONAL F  No No No	No No No PRODUCT INFORMATION OF Sale Bottle Box/Carton	If yes, attach FION  ORDER INFO  What is the leading to the second of th	RMATION NDC selling unit? ne Carton. The Carton	n FDA	Item:		Initial shelf li	Fe at launch (if  PACKING INFO	ORMATION smts.)		# Pieces:
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Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct Ship Item	distributor? de?  ADDITIONAL F  No No No No	No N	If yes, attach FION  ORDER INFO  What is the l  25 Vials in or 55150-200-1  (Write-in, e.g.	RMATION NDC selling unit? ne Carton. The Carton	n FDA	Box/	Weight Lbs.	Initial shelf li  ITEM AND  Dim  Depth	PACKING INFo	DRMATION smts.) Width:		# Pieces:  Carton (25 Vials) Case
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Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	Direct Ship Item  Direct Ship Item	ADDITIONAL F  NO NO NO NO NO NO NO	No N	If yes, attack FION  ORDER INFO  What is the last of t	RMATION NDC selling unit? ne Carton. The Carton 0 g. 1 Box of 10 Vials) der quantity? many of which packa	NDC No. is	Box/ Carton:	Weight Lbs.  1.39705(Carto n contains 25 Viale)  12.464	Initial shelf li  ITEM AND Dim Depth  3.353 (Carton	PACKING INFO ensions (US m Height  2.4400 (Carton contains 25 6.2992	DRMATION smts.) Width:		# Pieces:  Carton (25 Vials) Case
Is product sold by manu Are any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item  Direct Ship Item	distributor? de?  ADDITIONAL F  No No No No	No N	If yes, attack FION  ORDER INFO  What is the lactory of the state of t	RMATION NDC selling unit? The Carton. The Carton 0 The Carton of 10 Vials) The quantity? The carton of which packate the carton of the carton	NDC No. is	Box/ Carton: Case:	Weight Lbs.  1.39700(Carto n contains 25	Initial shelf lit  ITEM AND  Dim  Depth  Carton  Contains 25  11.811	PACKING INFo ensions (US m Height (Carton contains 25 6.2992	DRMATION smts.) Width:		# Pieces:  Carton (25 Vials) Case (Two 3 Ply Porsear
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© August 2014			Intr	roduction Type:	N	lew Item			Final Version		Date:		
		Р	RODUCT INFORMATIO	ON					SPECIAL HAI	NDLING AND S	TORAGE REQL	JIREMENTS*	
Company Name:	AuroMedics Pharma	LLC			Application:	AND	PΑ	a. Temperat	ure – Indicate ti	he USP tempera	ature range for	this product.	
Application Number f			205612			1			I. Freezer – betv	veen -25 and -10	) C (-13° – 14° F	=)	
DUNS:	,								II. Cold – betwee		,	,	
Rx Product/Proprietary	Name:	Ronivacaine H	ydrochloride Injection, U	SP 1% 200 mg/20	ml (10 mg/ml )				III. Cool – betwee	•	,		
NDC:	55150-201-20	rtopivadame i i	yaroomonae injection, e-	UPC:	355150201204				IV. Controlled R	,	,	° – 77° F)	
CVX Code:	00100 201 20			MVX Code:						cursions between			
Description:	Ponivacaine Hydrock	loride Injection I	USP 1% 200 mg/20 mL (	(10 mg/ml )					V. Avoid Excess		,		
Description.	Ropivacame riyuroci	nonde injection, t	03F 1/8 200 Hig/20 HiL (	(10 mg/mb)					VI. Other Tempe			,	
Active ingredients:									(write in)	ratare range re	equirement		1
									VII. No Requirer	nent			1
URL for Additional Prod	duct Information:	www.auromedi	ics.com					<u> </u>					
Address:	6 Wheeling Road			Address 2:				b. Contact f	or temperature	excursion ques	stions:		
City:	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas	4			
Key Contact:	,		Email:			!			r: 732-823-412	2			
Phone Number:	888-238-7880		Fax:	732-355-9449	)			Is this prod	luct to be shippe	d to customers	on ice?	No	
		FOR (	GENERIC DRUG PROD	DUCTS				Is this prod	duct to be shippe	d to customers	on dry ice?	No	_
I. Orange Book Rating:	AP		II. Brand Name:	Naropin									-
III. Generic Equivalent fo		ropivacaine	II. Brand Hame.	тчагорит				c Special re	gulations for p	roduct in certai	in states?	No	
III. Generic Equivalent id		_	AIN SECURITY ACT (DS	CCCA) INFORMAT	ION				•				-
			<u> </u>	SCSA) INFORMATI	ION			Special re	turns requiremen	its for this produ	Ct ?	No	-
Does supplier meet DS0	CSA definition of man	ufacturer?	Yes	_									
Is product exempt from	DSCSA?	No	_					d. Store pro	duct (unit of sa	ale) upright?		No	_
If yes, select exemption	on:							Protect p	roduct (unit of	sale) from light	?	No	
Other exemption - Wr	rite in:												_
Is product repackaged?	,	No	# V	inal product puro	haaad diraat fram m			e. Shelf life:	24	Months			
		110	it Yes, was orig	iliai product purc	hased direct from m	itr?		e. Shell life.	2-1				
Is product sold by manu			if Yes, was orig No	iliai product purc	nased direct from m	itr?		e. Sileli ille.		ife at launch (if	different):		Months
	ufacturer's exclusive	distributor?		<u> </u>	documentation from	_		e. Sileli lile.			different):		Months
Is product sold by manu	ufacturer's exclusive	distributor? de?	No	If yes, attach		_		e. Shell lile.	Initial shelf I		,		Months
Is product sold by manu Are any waivers granted	ufacturer's exclusive	distributor? de?	No No	If yes, attach	documentation fron	_			Initial shelf I	ife at launch (if	ORMATION	Volume	
Is product sold by manu	ufacturer's exclusive o	distributor? de?	No No	If yes, attach	documentation fron	_		Weight Lbs	Initial shelf I	PACKING INF	ORMATION	Volume (Cube)	Months # Pieces:
Is product sold by manu Are any waivers granted Is the Product	ufacturer's exclusive o	distributor? de? ADDITIONAL F	No No PRODUCT INFORMATION	If yes, attach ON ORDER INFOR What is the N	documentation fron	n FDA	ltom:		Initial shelf I  ITEM AND  Dim	ife at launch (if	ORMATION ismts.)		
Is product sold by manu Are any waivers granted Is the Product Legend Device?	ufacturer's exclusive o	distributor? de? ADDITIONAL F	No No PRODUCT INFORMATION Unit of Sale	If yes, attach ON ORDER INFOR What is the N	documentation from  RMATION  IDC selling unit?  e Carton. The Carton	n FDA	Item:		Initial shelf I  ITEM AND  Dim	PACKING INF	ORMATION ismts.)		
Is product sold by manuare any waivers granted Is the Product Legend Device? State Control?	ufacturer's exclusive o	distributor? de?  ADDITIONAL F  No No No No	No No No PRODUCT INFORMATION Unit of Sale Bottle	on or	documentation from  RMATION  IDC selling unit?  e Carton. The Carton	n FDA	Box/	Weight Lbs	Initial shelf I  ITEM AND  Dim  Depth	PACKING INF D PACKING INF nensions (US m Height	ORMATION  Ismts.)  Width:		# Pieces:
Is product sold by manuare any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	ufacturer's exclusive o	distributor? de?  ADDITIONAL F  No No No	No No No PRODUCT INFORMATION Unit of Sale  Bottle x Box/Carton Ampule Glass	If yes, attach ON ORDER INFOR What is the N 25 Vials in one 55150-201-20 (Write-in, e.g.	RMATION  RMATION  RMC selling unit?  e Carton. The Carton in the Carton	n FDA			Initial shelf I  ITEM AND  Dim	PACKING INF	ORMATION ismts.)		# Pieces:
Is product sold by manuare any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	ufacturer's exclusive of for product ID/barco	distributor? de?  ADDITIONAL F  No No No No	No No No PRODUCT INFORMATION IN THE INTERPOLATION INTERPOL	on or	RMATION  RMATION  RMC selling unit?  e Carton. The Carton in the Carton	n FDA	Box/	Weight Lbs	Initial shelf I  ITEM AND  Dim  Depth	PACKING INF D PACKING INF nensions (US m Height	ORMATION  Ismts.)  Width:		# Pieces:
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Is product sold by manuare any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narco	ufacturer's exclusive of d for product ID/barco  Direct Ship Item  Litic) Code:	distributor? de?  ADDITIONAL F  No No No No No No	No N	If yes, attach ON ORDER INFOR What is the N 25 Vials in one 55150-201-20 (Write-in, e.g. Minimum ord	RMATION  IDC selling unit? e Carton. The Carton of the car	NDC No. is	Box/ Carton:	Weight Lbs  2.34030 (Carton contains 26 12.307 771.430 (rd Sea)	Initial shelf I  ITEM AND Dim Depth  O.77 (Canonicontains 25	D PACKING INF Densions (US m Height  2.03 (Canton contains 25 Vials)  8.661  59.37 (For Sea)	ORMATION Ismts.) Width: contains 25		# Pieces:  Canton (23 Vials)  5 5 7 2 5 5 5 7 6 5 7 7 8 7 9 9 7 7 8 2 7 (60 Shippers
Is product sold by manuare any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narco	ufacturer's exclusive of d for product ID/barco  Direct Ship Item  Litic) Code:	distributor? de?  ADDITIONAL F  No No No No	No N	If yes, attach ON ORDER INFOR What is the N 25 Vials in one 55150-201-20 (Write-in, e.g. Minimum ord	RMATION IDC selling unit? e Carton. The Carton i  1 Box of 10 Vials) der quantity?	NDC No. is	Box/ Carton: Case: Pallet:	Weight Lbs  (Carton contains 26  12.307  771.430 (10 Sea)  1140.664 (E	Initial shelf I  ITEM AND Dim Depth  O.77 (Canon contains 25 Viole)  15.157	PACKING INF D PACKING INF Densions (US m Height  2.03 (Canton contains 25 Viole)  8.661  39.37 (FOI	ORMATION USINTS.) Width:  U.17 (Carton contains 25 Vials)  8.071		# Pieces:  Vials)  5-72-8T (Four 3 Ply  Porsear
Is product sold by manuare any waivers granted  Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narco	ufacturer's exclusive of d for product ID/barco  Direct Ship Item  Litic) Code:	distributor? de?  ADDITIONAL F  No No No No No No	No N	If yes, attach ON ORDER INFOR What is the N 25 Vials in one 55150-201-20 (Write-in, e.g. Minimum ord If Yes, how m	RMATION RDC selling unit? e Carton. The Carton 1. 1 Box of 10 Vials) der quantity? nany of which packa Each	NDC No. is	Box/ Carton: Case:	Weight Lbs  2.34030 (Carton contains 26 12.307 771.430 (rd Sea)	Initial shelf I  ITEM AND Dim Depth  O.77 (Canon contains 25 Viole)  15.157	PACKING INF Densions (US m Height  2.00 (Calton contains 25 Viole) 8.661 39.07 (FOI Sea) 56.89 (For Air)	ORMATION USINTS.) Width:  U.17 (Carton contains 25 Vials)  8.071		# Pieces:  Canton (23 Vials)  5 5 7 2 5 5 5 7 6 5 7 7 8 7 9 9 7 7 8 2 7 (60 Shippers
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