

Standard Pharmaceutical Product Information (Rx Product Only)

							Introdu	uction Type:		New Item		Final Version			Date:		
				PRODUCT INFORI	MATION							SPECIAL HANDL	ING AND ST	ORAGE REQI	UIREMENTS	S*	
Company Name: Application Number for NDA	AuroMedics Pharma		d dovi					Application	on:	ANDA		licate the USP temper	ature range f			een 20 and 25	C (68° 77° !
	VANDA/BLA (drug);	PWIA/5TU(K)(Me	a device):			7					-	erature Range		Controlled K	DOITI - DELWE	een zo and zo	0 (00 - 77)
DUNS: Proprietary Name (If Applicate	la) and Fatabliahad	Name	DI IDIVAÇA	INE HCL INJECTION	LICE O FOOT (OF	0	e/eal \\ [E0 eal	Multi Dass \	/:el1			Temperature Range Re write in)	quirement				1
Selling Unit NDC:	55150-250-50	Name.	BUFIVACA	Individual Unit ND		55150-250-50			15025050	19	-	write iii)					J
UDI				CVX Code:			MVX C				Is this	product to be shipped t	o customers	on ice?			
Description:	BUPIVACAINE HCL	INJECTION USF	P 0.50% (250	0mg/50mL (5 mg/mL))	[50 mL Multi Do	ose Vial]					Is this	product to be shipped t	o customers	on dry ice?			
Active Ingredient(s):												rature excursion ques	stions:				
URL for Additional Product In	formation:	www.auromedi	cs com								Name Numb						
Address:	279 Princeton-Hights		00.00111				Address 2:	: [E-mail:					
City:	East Windsor					State:	NJ	Zip:	C	08520							
Key Contact:	000 000 7000					Email: Fax:	722 255 0	110				s for product in any s		-10		No No	-
Phone Number: Product Therapeutic Classific	888-238-7880					гах.	732-355-94	449			Specia	al returns requirements	tor this produ	Ct?		No	-
r roduct merapeutic classific	Jation.					_					d. Store product (un	it of sale) upright?				Yes	
ADDITIONAL	L PRODUCT INFORM	MATION				F	PRODUCT DI	ESCRIPTION	INFORM	ATION		ct product (unit of sale) from light?			No	=
Is the Product											e. Shelf life:					24	Months
a legend device?			No			Size:					Initial	shelf life at launch (if	different):				Months
reverse numbered?			No			0.20.							NDDER INFO	DMATION			
co-licensed?		Direct-Ship On	No Iv			Strength:							RDER INFO	RWATION			
Is the Product			,			Dosago Form					Unit o	f Sale		What is the	NDC selling	g unit?	
						Dosage Form						Bottle				dose vials in E	-Flute box)
If Unit Dose, is item bar coded	d to unit dose for hosp	oital scanning?					_				ıII	Box/Carton Ampule		(Write-in, e.	.g. 1 Box of 1	10 Vials)	
If Unit Dose NDC, indicate NE	OC here:					Product Shap	e:					Glass		Minimum or	rder quantity	y?	
Occupation of October		1				Product Color	r:					Tube					
Country of Origin		India									x	Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of wh	ich package	tvne?
Is this product covered under	the Trade Agreement	ts Act (TAA)?	No			Product Impri	int:					Vial Powder Sql			Each	non paonago	.,,,,,
												Vial Power Multi		25	Inner/Cartor	n/Pack	
			-	OR GENERIC DRUG	PPODUCTS							Other: Write In	1	100	Case		
			•	OR GENERIO BROS	TRODUCTO								_				
					_	Auth	orized Generi			Generic, other section			MACY ORDE	ER / BILL UNI			
I. Orange Book Rating:	AP	Ini.	ta atta a					ileid	s are not a	аррисавіе	Rec. sell unit to cust	omer?		Rx billing u		nacy:	
II. Generic Equivalent to What	t Brand?:	Bupivacaine In	jection								(Write-in, e.g. 1 Vial)				Each Gram		
		DRU	G SUPPLY	CHAIN SECURITY AC	CT (DSCSA) INF	ORMATION					(vviite iii, e.g. i viai)				Milliliter		
											,						
Does supplier meet DSCSA d Is product exempt from DSCS		turer?	No	Yes	GL	.N:	035515000	00005				IIEM A	ND PACKING	INFORMATI	ON		
If yes, select exemption:					_							Mainht I ha	Dime	nsions (US m	ısmts.)	Volume	# Diagon.
Other exemption - Write in:												Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged? Is product sold by manufactu	rer's exclusive distri	ibutor?	No	No		res, was origin om mfr?	al product pi	urchased dir	ect		Item:				i	0	
Has FDA granted waiver/exce	eption/exemption for	product?		No	lf y	es, attach doci	umentation f	rom FDA.			Box/Carton/Bundle/ Inner Pack:	6.0108	9.29	3.58	9.29	308.968678	5 Vials/Carto
				GTIN PRODUCT INFO	ORMATION Saleable						Case:	25.68	19.685	8.858	10.039	1750.49772	4 Cartons/Cas
				Level	Unit			Qua		GTIN-14	Pallet:	Air 1265.679	47.24	57.36	39.37	106680 354	l8 cases/palle
Serialized?			x Ite			2D		near 1		10355150250506					39.37	100000.334	io cases/palle
If not, when? Items aggregated?		_		ox/Carton/Bundle/Inner Pack ase	25s	2D 2D		near 2:		30355150250500 50355150250504	UPC:	Case: Carton:	503551502 303551502				
nems aggregates:		_		allet		2D		near 48		70355150250504		•	000001002				
						2D		near			COS	T INFORMATION			WHOLESAL	LER USE ON	_Y:
						2D		near	_								
			—— -			2D 2D		near			Regular Cost Invoice Cost (WAC)	(\$)	\$57.45	Vendor #: Whsl. Code	#:		
		ļ									Federal Excise Tax I		Q07.40	Fineline Co			
											As of date:	9/12/2017					
			*		NATA OUEET (C	200)		OKA OF INCO	DT LASS	I AND DUOTO CE SE	ODLIGT DAOKAONIS :	DARGORE		1			
*Please provide any additional	al information on pag	ge 2.	Atta	acn copy of SAFETY D	JATA SHEET (S	or non haza (כעם				EL AND PHOTO OF PR pp Ship Only.	ODUCT PACKAGING and Signa						



Standard Pharmaceutical Product Information (Rx Product Only)

							Intro	duction Type):	New Item			Final Version			Date:		
				PRODUCT IN	FORMATION								SPECIAL HANDL	ING AND STO	RAGE REQ	JIREMENTS	*	
Company Name:	AuroMedics Pharma	NIC.						Applicat	lion:	ANDA		manatura Indi						
Company Name:			d daylas).			1		Applicat	tion:	ANDA	a. ren		icate the USP temper	ature range t			on 20 and 25	C (68° – 77° F
Application Number for ND	A/ANDA/BLA (drug);	; PMA/510(K)(me	a device):									rempe	rature Range		Controlled R	oom – betwe	en zo and zo	0 (00 - 77 1
DUNS:												Other T	emperature Range Re	quirement				_
Proprietary Name (If Applical		d Name:	BUPIVACA	AINE HCL INJECT								(v	vrite in)					
Selling Unit NDC:	55150-249-50		1	Individual Uni	t NDC:	55150-249-5	0	UPC: '35	515024950)3								=
UDI				CVX Code:			MVX	Code:				Is this p	product to be shipped t	o customers	n ice?			
Description:	BUPIVACAINE HCL	INJECTION USE	2 0.25% (12)	5mg/50mL (2.5 m	ng/mL) [50 mL Mu	lti Dose Viall						Is this r	product to be shipped t	o customers	n dry ice?			
				. 3 (.	5 /1										. ,			_
Active Ingredient(s):		www.auromedi	cs.com								b. Cor	tact for temper	ature excursion ques	stions:				
3 (.,		www.auromedi	cs.com									Name:						
URL for Additional Product In	nformation:	www.auromedi	cs.com									Numbe	er:					
Address:	279 Princeton-Hights	stown Road					Address	2:				Group	E-mail:					
City:	East Windsor					State:	NJ	Zip:		08520								-
Key Contact:						Email:					c. Spe	cial regulations	s for product in any s	tates?			No	
Phone Number:	888-238-7880					Fax:	732-355-	9449				Special	I returns requirements	for this produ	t?		No	_
Product Therapeutic Classific	ication:																	_
·											d. Sto	e product (uni	t of sale) upright?				Yes	
ADDITIONA	L PRODUCT INFORI	MATION					PRODUCT	DESCRIPTION	N INFORM	ATION			t product (unit of sale) from light?			No	-
Is the Product											e. She			,			24	Months
a legend device?			No				Г				- e. sne		shelf life at launch (if	difforont):			24	Months
reverse numbered?			No			Size:						miliais	sileii ille at laulicii (il	umerent).				Months
co-licensed?			No				-						(RDER INFO	MATION			
Is the Product		Direct-Ship On				Strength:												
Is the Product		Birott Omp On					-				- 11	Unit of	Sale		What is the	NDC selling	unit?	
io allo i roddollii						Dosage For	m:					0	Bottle				lose vials in E	-Flute box)
							_				-'		Box/Carton		(Write-in, e.			
If Unit Dose, is item bar code	ed to unit dose for hos	pital scanning?					Г				7 11		Ampule		(9		
If Unit Dose NDC, indicate NI	DC here:					Product Sha	ape:						Glass		Minimum o	der quantity	/?	
.,													Tube				•	
Country of Origin		India				Product Col	or:						Vial Liquid Sgl					
Is this product covered under	T	40 A at /TA A \2				Product Imp						x	Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
is this product covered under	rine Trade Agreemen	IIS ACI (TAA)?	No			Product imp	orint:						Vial Powder Sql		1	Each		
							_						Vial Power Multi		25	Inner/Cartor	n/Pack	
-													Other: Write In		100	Case		
			F	FOR GENERIC DE	RUG PRODUCTS													
						Au	thorized Gene			Generic, other section	1		PHAR	MACY ORDE	R / BILL UN	T		
I. Orange Book Rating:	AP							field	lds are not	applicable	Rec. s	ell unit to custo	omer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to Wha	at Brand?:	Bupivacaine In	jection													Each		
											(Write	-in, e.g. 1 Vial)		- '		Gram		
		DRU	G SUPPLY (CHAIN SECURIT	Y ACT (DSCSA)	INFORMATION										Milliliter		
											_,							
Does supplier meet DSCSA of		cturer?		Yes		GLN:	03551500	000005					ITEM A	ND PACKING	INFORMAT	ON		
Is product exempt from DSC	SA?		No)										D :				
If yes, select exemption: Other exemption - Write in:													Weight Lbs.		sions (US m		Volume (Cube)	# Pieces:
Is product repackaged?			No			If Yes, was original			ina at		Item:			Depth	Height	Width		
Is product repackaged:	urar'e avalueiva dieti	ributor?		No		from mfr?	mai product	purchaseu ui	iieci _		_ Item.						0	
Has FDA granted waiver/exce				No		If yes, attach do	cumentation	from FDA			Boy/C	arton/Bundle/		1				
rias i DA grantea warver/exec	eption/exemption for	i product.				ii yes, attaon ac	camemation	monin DA.			Inner		6.0108	9.29	3.58	9.29	308.968678	5 Vials/Carto
				GTIN PRODUCT	INFORMATION						Case:			1				
					Saleable						- Case		25.68	19.685	8.858	10.039	1750.49772	4 Cartons/Cas
				Level	Unit			Qua	antity	GTIN-14	Pallet:		1: 100= 0=0					
Serialized?			x Ite	em		2D				10355150249500	7111		Air 1265.679	47.24	57.36	39.37	106680.354	18 cases/palle
If not, when?				lox/Carton/Bundle/Inner	r Pack 25s	2D		Linear 2	25	30355150249504	UPC:		Case:	5035515024	9508			1
Items aggregated?				ase		2D				50355150249508			Carton:	3035515024				
		_		allet		2D				70355150249502			•	1				
						2D		Linear				cos	T INFORMATION	_		WHOLESAL	ER USE ONI	LY:
						2D		Linear										
						2D		Linear			Regula	ar Cost			Vendor #:			
11						2D		Linear				e Cost (WAC) (\$)	\$68.65	Whsl. Code	#:		
											Federa	al Excise Tax P	er Unit of Sale		Fineline Co	de:		
											As of o	late:	9/12/2017					
											As of o	late:						
*Please provide any addition.			Atta	ach copy of SAFE	ETY DATA SHEE	T (SDS) or non ha		ACKAGE INS		EL AND PHOTO OF P			9/12/2017					



		Date:	
New Item Promotion/Deal Open Stock	Post Launch Change		

Final Version

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PRODUCT INFORMATION PRODUCT INFORMATION AND						SPECIAL I	HANDLING A	ND STORA	GE REQUIR	EMENTS*	
Company Name: AuroMedics Phar	ma LLC		NDA A	NDA BLA Med Device #	a. Tempera	ture – Indicate	the USP tem	perature rar	nge for this p	roduct.	
Application number	r for NDA/ A	NDA/ BLA, Med Device:				I. Freezer – b	etween -25 ar	nd -10 C (-13	° – 14° F)		
Rx Product / Proprietary Name:		BUPIVACAINE HYDR	OCHLORIDE IN	JECTION, USP 0.5% (5 mg/mL)	1 =	II. Cold - bety	ween 2 and 8	C (36° – 46°	F) .		
NDC: 55150-169-10		UPC:		, , , , , , , , , , , , , , , , , , ,	1	III. Cool – bet		•	•		
CVX Code:		MVX Code:			1	IV. Controlled		•	•	77° F)	
	ADBUCHI C		P 0 5% /5 ma/m	L L) [10 mL Single Dose Vial]		allows for ex			•	•	
BOI WADAIRE III	DICOULLE	DIVIDE INCLUTION, CO	1 0.5 /0 (5 mg/m	L) [10 IIIL Olligie Dose Vial]		V. Avoid Exce			•	O F)	
Andhar Inama Banta									` ,		
Active ingredients:						VI. Other Ter	-	nge Require	ment		
		1					(write in)				
JRL for additional product information				,		VII. No Requi					
Address: 6 Wheeling Road			Address 2:		b. Contact	for temperatur	re excursion	questions:			
City: Dayton, NJ 08810)	State:	Zip:		Name:				Number:		
Key Contact:		Email:									
Phone Number:		Fax			Is this pr	oduct to be sh	nipped to cus	tomers on ic	e?	O Yes	No
	FOR (GENERIC DRUG PRO	DUCTS		Is this pr	roduct to be sh	nipped to cus	tomers on di	ry ice?	O Yes	No
. Orange Book Rating:		II. Brand Name:									
II. Generic Equivalent for Brand:					c. Special r	regulations for	this product	in certain st	ates?	○ *Yes	s No
	ADDITIO	NAL PRODUCT INFO	RMATION		Special r	eturns require	ements for thi	s product?		O *Yes	_
	Level	How?		GTIN-14	1	-		-			
Serialized? Oyes Ono	Item	2D Linear	RFID		d. Store pr	oduct (unit of	sale) upright	?		○ Yes	No
3 162 3 116	Case	2D Linear	RFID	50355150169103	-	product (unit o	,			O Yes	_
	Pallet		RFID	70355150169107			,	3		O les	© 140
s the Product					e. Shelf life):		Months			
Direct Ship Ite	em 🗌	Direct and Drop Ship	Drop Ship	only item (See new page 3.)		Initial shelf lif					Months
a Legend Device?	○ No										
a State Control?	O No			ITEM ANI	PACKING	INFORMATIO	ON				
ARCOS reportable?	O No		Order Info	rmation			Dimen	sions (US m	smts.)	Volume	
Co-Licensed? Yes	O No	Unit of Sale	What is the ND		-	Weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:
Repackaged? Yes	O No	Bottle	1 Box of 25 Via	•						, í	
Controlled Substance? Yes	O No	Box / Carton			Item:					0	
Schedule No.?	O NO	Ampule	(Wri	te-in, e.g. 1 Box of 10 Vials)	Box/	4.00	5.045			22 - 242-	
(incl. N for no	n-narcotic)	Glass	Minimum orde		Carton:	1.68	5.315	2.362	5.315	66.72467	25 vials
		Tube	W		0	40.70	44.00	5.540	44.00	200 0000	200 vials
Hazardous Material / Cytotoxic Agen	t?	✓ Vial Liquid Sgl	if Yes, now ma	ny of which package type?	Case:	13.78	11.22	5.512	11.22	693.8969	8x25 vials
○ *Yes	No	☐ Vial Liquid Multil		Eac		1000 50	4= 044	40 = 4=			
s Item O Unit Dose O Unit o	f I Isa	Vial Powder Sql		Inner / Carton	Pallet:	1029.56	47.244	42.717	39.37	79453.46	72 Shippers
f Unit Dose, is item bar coded to unit do		Vial Powder Multi Other: Write In		Case		Case:					
nospital scanning? Yes	○ No	Other. Write in			UPC:	Carton:					
s it reverse numbered? Yes	O No	PHARMACY ORDE	R / BILL UNIT	Other Product Information	on			COST INFO	RMATION		
Tes	O NO	Rec. sell unit to custor		Size/Strength/Form:		Regular Cos	t Per Unit of			Federal Fx	ise Tax Per
WHOLESALER USE ONLY	Y:					Sale		Invoice Cos	st (WAC) (\$)	Unit of Sale	
/endor #:		(Write-in, e.g	. 1 Vial)	Product Shape:			(*)				
Whsl. Code #:		Rx billing unit to pharr		Product Color:							
Fineline Code:		Each Gram	Millilite	Product Imprint:							
		Lacii Laciii		i roduct imprint.							



New Item	Promotion/Deal	Open Stock	Post Launch Change	Date:	
INEW ITEIII	Promotion/Dear	Open Stock	rost Laurion charige		

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PRODUCT INFORMATION							SPECIAL	HANDLING A	AND STORA	GE REQUIR	EMENTS*	
Company Name:	AuroMedics Phar	ma LLC		NDA A	NDA BLA Med Device 7	a. Tempera	ature – Indicat	e the USP ten	nperature rai	nge for this p	roduct.	
	Application number	r for NDA/ A	NDA/ BLA, Med Devi	ce:			I. Freezer – b		-	-		
Rx Product / Propr	••				JECTION, USP 0.5% (5 mg/mL)	7	II. Cold - bet		•	•		
	55150-170-30		UPC:		· · · · · · · · · · · · · · · · · · ·		III. Cool – bet		•	•		
	CVX Code:		MVX Code			-	IV. Controlle		•	•	77° F)	
Description:		YDROCHI C			L) [30 mL Single Dose Vial]			cursions bet		•	•	
Description.	BOT WASAINE IT	DICOGNEC	orribe intocorrort,	501 0.070 (0 mg/m	iz) [00 mz omgie zooc viai]			essive Heat –		•	.0 1)	
Antivo inc	rradionto.									. ,		
Active int	gredients:						vi. Other re	mperature Ra	inge Require	ment		
			l					(write in)				
URL for additional				A 1.1		┥ └ .	VII. No Requi					
Address:	6 Wheeling Road		Ia I	Address 2:			for temperatu	re excursion	questions:			
City:	Dayton, NJ 08810)	State:	Zip		Name:				Number:		
Key Contact:			Em	ail:								
Phone Number:				ax:		Is this p	roduct to be sl	hipped to cus	tomers on ic	e?	O Yes	● No
		FOR (GENERIC DRUG P	RODUCTS		Is this p	roduct to be sl	hipped to cus	tomers on d	ry ice?	O Yes	No
I. Orange Book Ra	ting:		II. Brand Name:									
III. Generic Equival	lent for Brand:					c. Special ı	regulations for	r this product	in certain st	ates?	○ *Ye	s No
		ADDITIO	NAL PRODUCT IN	FORMATION		Special i	returns require	ements for th	is product?		○ *Ye	s No
		Level	How?		GTIN-14							
Serialized?	O Yes O No	Item	2D Line	ear RFID		d. Store pi	roduct (unit of	sale) upright	?		○ Yes	● No
		Case	2D Line		50355150170307	Protect	product (unit	of sale) from	light?		○ Yes	_
		Pallet	2D Line	ear RFID	70355150170301			•	_		0 103	0 110
Is the Product						e. Shelf life	e:		Months			
	Direct Ship Ite	em	Direct and Drop Ship	☐ Drop Ship	o only item (See new page 3.)		Initial shelf li					Months
a Legend Device?	○ Yes	○ No						•				
a State Control?	O Yes	O No			ITEM AN	ID PACKING	INFORMATIO	ON				
ARCOS reportable		O No		Order Info	ormation		M/-1-0-4-1-1	Dimen	sions (US m	smts.)	Volume	" D'
Co-Licensed?	O Yes	O No	Unit of Sale	What is the ND	C selling unit?		Weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:
Repackaged?	O Yes	O No	Bottle	1 Box of 25 Via	als	lt a man						
Controlled Substar		O No	Box / Carton			Item:					0	
Schedule No.?	N		Ampule	(Wr	ite-in, e.g. 1 Box of 10 Vials)	Box/	3.44	C CO2	3.15	C CO2	444 4000	25 Vials
	(incl. N for no	n-narcotic)	Glass	Minimum orde	er quantity? O Yes O No	Carton:	3.44	6.693	3.15	6.693	141.1082	25 Viais
			Tube	If Vos how ma	iny of which package type?	Case:	16.49	14.173	4.331	14.173	869.985	100 vials
Hazardous Materia	II / Cytotoxic Agen	t?	✓ Vial Liquid Sgl	ii res, now ma	iny of which package type?	Case.	10.49	14.173	4.331	14.173	009.900	2x2x25
	○ *Yes	No	Vial Liquid Multil		Eac	Dellet	020.02	47.044	45 470	20.27	04577.75	40 Chinner
Is Item O Unit	Dose O Unit o	f Use	Vial Powder Sql Vial Powder Multi		Inner / Carton	Pallet:	829.02	47.244	45.472	39.37	84577.75	48 Shippers
If Unit Dose, is item b			Other: Write In		Case		Case:					L
hospital scanning?	○ Yes	○ No	Other: Write in			UPC:	Carton:					
ls it reverse numbe	ered? O Yes	○ No	PHARMACY ORI	DER / BILL UNIT	Other Product Informat	ion			COST INFO	RMATION		
	0 103	O 110	Rec. sell unit to cus	tomer?	Size/Strength/Form:		Regular Cos	t Per Unit of			Federal Exc	ise Tax Per
WHOLES	SALER USE ONLY	/ :			3 3 1		_	e (\$)	Invoice Co	st (WAC) (\$)	Unit of Sale	
Vendor #:			(Write-in,	e.g. 1 Vial)	Product Shape:							
Whsl. Code #:			Rx billing unit to ph		Product Color:							
Fineline Code:			Each Gram		Product Imprint:							
					I							



New Item	Promotion/Deal	Open Stock	Post Launch Change	Date:	

Final Version

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Р	RODUCT INFORMATI	ON				SPECIAL	HANDLING A	AND STORA	GE REQUIR	EMENTS*	
Company Name: AuroMedics Pharma LLC		NDA AN	IDA BLA	Med Device ₹	a. Tempera	ture – Indicat	e the USP tem	nperature rar	nge for this p	roduct.	
Application number for NDA/ A	NDA/ BLA. Med Device:				1 —		etween -25 aı	-			
··	BUPIVACAINE HYDRO	CHLORIDE IN.	JECTION, USP 0.2	25% (2.5 mg/mL)	1 =		ween 2 and 8	•	•		
NDC: 55150-167-10	UPC:		, ,	, , , , , , , , , , , , , , , , , , ,	1		tween 8 and 1	•	•		
CVX Code:	MVX Code:						d Room – bet	•	,	77° F)	
Description: BUPIVACAINE HYDROCHLO		0 0 25% (2 5 mg	/ml \ [10 ml Sing	le Dose Viall	1		cursions betw		•	•	
BOT WADAINE TO BROOTER	SKIDE INDESTIGN, OUI	0.23 /0 (2.3 mg	ine) [10 ine onig	ic Dose viaij			essive Heat –		•	ю г)	
Active ingredients					 						
Active ingredients:						vi. Other rei	mperature Ra	nge Require	ment		
							(write in)				
URL for additional product information:	1	4.1.				VII. No Requi					
Address: 6 Wheeling Road	1-	Address 2:			1	for temperatu	re excursion	questions:			
City: Dayton, NJ 08810	State:	Zip:			Name:				Number:		
Key Contact:	Email:				1						
Phone Number:	Fax:				Is this pr	oduct to be sl	hipped to cus	tomers on ic	e?	O Yes	● No
FOR (GENERIC DRUG PRO	DUCTS			Is this pr	oduct to be sl	hipped to cus	tomers on d	ry ice?	○ Yes	No
I. Orange Book Rating:	II. Brand Name:										
III. Generic Equivalent for Brand:					c. Special r	egulations for	r this product	in certain st	ates?	○ *Yes	s No
ADDITIO	NAL PRODUCT INFO	RMATION			Special r	eturns require	ements for thi	is product?		○ *Yes	s No
Level	How?		GTIN-14		1						
Serialized? Oyes Ono Item	2D Linear	RFID			d. Store pr	oduct (unit of	sale) upright	?		○ Yes	No
Case		RFID	50355150167109	9	Protect	product (unit	of sale) from	light?		O Yes	~
Pallet		RFID	7035515016710	3	1	. ,	•			O Tes	O 110
Is the Product					e. Shelf life):		Months			
	Direct and Drop Ship	Drop Ship	only item (See new	v page 3.)			fe at launch (i	4			Months
a Legend Device? Ores No							`			<u> </u>	
a State Control? Yes No				ITEM AND	PACKING	INFORMATIO	ON				
ARCOS reportable?		Order Info	rmation				Dimen	sions (US m	smts.)	Volume	
Co-Licensed?	Unit of Sale	What is the NDC				Weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:
Repackaged?	Bottle	1 Box of 25 Vial	s							<u> </u>	
Controlled Substance?	Box / Carton				Item:					0	
Schedule No.? N	Ampule	(Writ	e-in, e.g. 1 Box of 1	0 Vials)	Box/	4.00	5.045	0.000	5.045	66 70467	05
(incl. N for non-narcotic)		Minimum orde	r quantity?	Yes O No	Carton:	1.68	5.315	2.362	5.315	66.72467	25 vials
	Tube	If Vac have man	av af whiah maaka	tumo 2	Casa	42.70	44.00	E 540	44.00	602 0060	200 vials
Hazardous Material / Cytotoxic Agent?	Widi Liquid 591	ir res, now mai	ny of which packa	ige type?	Case:	13.78	11.22	5.512	11.22	693.8969	8x25 vials
○ *Yes ● No	☐ Vial Liquid Multil		Eac		5.11.4	4000 50	47.044	40.747	00.07	70.450.40	70.01
Is Item O Unit Dose O Unit of Use	Vial Powder Sql		Inner / Carton		Pallet:	1029.56	47.244	42.717	39.37	79453.46	72 Shippers
If Unit Dose, is item bar coded to unit dose for	Vial Powder Multi Other: Write In		Case			Case:		<u> </u>			
hospital scanning?	U Other. Write in				UPC:	Carton:					
Is it reverse numbered?	PHARMACY ORDER	R / BILL UNIT	Other I	Product Information	n			COST INFO	RMATION		
	Rec. sell unit to custom		Size/Strength/Fo			Regular Cos	t Per Unit of	1	_	Federal Exc	ise Tax Per
WHOLESALER USE ONLY:			o g / 1			_	e (\$)	Invoice Cos	st (WAC) (\$)	Unit of Sale	
Vendor #:	(Write-in, e.g.	1 Vial)	Product Shape:				- \+/			J	
Whsl. Code #:	Rx billing unit to pharm		Product Color:			1					
Fineline Code:	Each Gram	Millilite	Product Imprint:			1					
	Lacii Lacii		i roduct impriit.								



New Item Promotion/Deal Open Stock Post Launch Change						
New Item Promotion/Doal Open Stock Post Launch Change	New Item	Promotion/Doal	Open Stock	Post Launch Change	Date:	

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PRODUCT INFORMATION							SPECIAL	HANDLING A	AND STORA	GE REQUIR	EMENTS*	
Company Name:	AuroMedics Phari	ma LLC		NDA A	NDA BLA Med Device 7	a. Tempera	ature – Indicate	e the USP ten	perature rar	nge for this p	roduct.	
	Application number	for NDA/ A	NDA/ BLA, Med Device:				I. Freezer – b		-	-		
Rx Product / Propr	• •		· · · · · · · · · · · · · · · · · · ·	OCHLORIDE IN.	JECTION, USP 0.25% (2.5 mg/mL)		II. Cold - bet		•	•		
	55150-168-30		UPC:			1 8	III. Cool – bet		•	•		
1100.	CVX Code:		MVX Code:				IV. Controlled		•	•	77° F)	
Description:		DBUCHI U		2 0 25% (2 5 mg	/mL) [30 mL Single Dose Vial]	-				•	•	
Description.	BOT WACAINE III	DIVOCITEO	MIDE INSECTION, USI	0.23 /6 (2.3 mg	mic) [30 mic Single Dose vial]			cursions bety		•	ю г)	
A a thoraction	and the sales							essive Heat –		` ,		
Active ing	gredients:						VI. Other Tel	mperature Ra	nge Require	ment		
								(write in)				
	product information	on:					VII. No Requi					
Address:	6 Wheeling Road			Address 2:		b. Contact	for temperatu	re excursion	questions:			
City:	Dayton, NJ 08810		State:	Zip:		Name:	:			Number:		
Key Contact:			Email:									
Phone Number:			Fax:			Is this p	roduct to be sl	hipped to cus	tomers on ic	e?	○ Yes	● No
		FOR G	SENERIC DRUG PRO	DUCTS		Is this p	roduct to be sl	hipped to cus	tomers on di	ry ice?	○ Yes	
I. Orange Book Rat	ting:		II. Brand Name:									
III. Generic Equival	lent for Brand:					c. Special	regulations for	r this product	in certain st	ates?	○ *Ye	s No
		ADDITIO	NAL PRODUCT INFO	RMATION		Special i	returns require	ements for thi	is product?		○ *Ye	_
		Level	How?		GTIN-14	7	•		•			
Serialized?	O Yes O No	Item	2D Linear	RFID		d. Store pi	roduct (unit of	sale) upright	?		○ Yes	No
	0 101 0 110	Case	2D Linear	RFID	50355150168304	-	product (unit	,			O Yes	_
		Pallet	2D Linear	RFID	70355150168308			,	3		O les	© 140
Is the Product						e. Shelf life	e:		Months			
	Direct Ship Ite	m 🗌	Direct and Drop Ship	Drop Ship	only item (See new page 3.)		Initial shelf li		4			Months
a Legend Device?	○ Yes	○ No						`				
a State Control?	O Yes	O No			ITEM AN	D PACKING	INFORMATIC	ON				
ARCOS reportable		O No		Order Info	rmation			Dimen	sions (US m	smts.)	Volume	
Co-Licensed?	O Yes	O No	Unit of Sale	What is the NDO			Weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:
Repackaged?	O Yes	O No	Bottle	1 Box of 25 Via	•						, ,	
Controlled Substar		O No	Box / Carton			Item:					0	
Schedule No.?	N	0 110	Ampule	(Wri	te-in, e.g. 1 Box of 10 Vials)	Box/	0.44	0.000	0.45	0.000	444 4000	05.1/2-1-
	(incl. N for no	n-narcotic)	Glass	Minimum orde	r quantity? O Yes O No	Carton:	3.44	6.693	3.15	6.693	141.1082	25 Vials
			Tube	lf Vaa haw ma	ny of which moderne time?	Casa	46.40	44472	4 224	44.472	000 005	100 vials
Hazardous Materia	al / Cytotoxic Agent	?	✓ Vial Liquid Sgl	ir res, now ma	ny of which package type?	Case:	16.49	14.173	4.331	14.173	869.985	2x2x25
	○ *Yes	No	☐ Vial Liquid Multil		Eac	5 11 4	200.00	47.044	45 470	00.07	0.4577.75	40.01
Is Item O Unit	Dose O Unit of	Use	Vial Powder Sql		Inner / Carton	Pallet:	829.02	47.244	45.472	39.37	84577.75	48 Shippers
	par coded to unit dos		Vial Powder Multi Other: Write In		Case		Case:					
hospital scanning?	○ Yes	○ No	Ottlet. Write III			UPC:	Carton:					
ls it reverse numbe		○ No	PHARMACY ORDER	R / BILL UNIT	Other Product Informati	on		ı	COST INFO	RMATION		
	0.00.		Rec. sell unit to custom	ner?	Size/Strength/Form:		Regular Cos	t Per Unit of	I		Federal Ex	ise Tax Per
WHOLES	SALER USE ONLY						_	e (\$)	Invoice Cos	st (WAC) (\$)	Unit of Sale	
Vendor #:			(Write-in, e.g.	1 Vial)	Product Shape:			.,,				
Whsl. Code #:			Rx billing unit to pharm		Product Color:							
Fineline Code:			Each Gram	Millilite	Product Imprint:		1					
					oadot impinit.							



Now Itom	Promotion/Deal Open Stock	Doct Launch Change	Date:	
new item	Promotion/Deal Deel Stock	rost Laurich Change		

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PRODUCT INFORMATION							SPECIAL	HANDLING A	AND STORA	GE REQUIR	EMENTS*	
Company Name:	AuroMedics Phar	rma LLC		NDA A	NDA BLA Med Device 7	a. Tempera	ature – Indicate	e the USP ten	nperature rar	nge for this p	roduct.	
· ·	Application numbe	r for NDA/ A	NDA/ BLA, Med Device):			I. Freezer – b		-	-		
Rx Product / Propr	• •		· · · · · · · · · · · · · · · · · · ·		JECTION, USP 0.75% (7.5 mg/mL	<u> </u>	II. Cold - bet		•	•		
	55150-171-10		UPC:	1	<u> </u>	4	III. Cool – bet		•	•		
1100.	CVX Code:		MVX Code:				IV. Controlled		•	•	77° F)	
Description:		ADBUCHI (SP 0.75% (7.5 m	l g/mL) [10 mL Single Dose Vial]			cursions bet		•	•	
Description.	BOI IVAOAINE II	IDINOGIILO	TRIDE INVESTIGIT, OF)	gille, [10 lile olligie bose vial]			essive Heat –		•	ю г)	
A address to a										` '		
Active int	gredients:						vi. Other rei	mperature Ra	nge Require	ment		
			I					(write in)				
URL for additional				1 411 0		4	VII. No Requi					
Address:	6 Wheeling Road		1 -	Address 2:			for temperatu	re excursion	questions:			
City:	Dayton, NJ 08810	0	State:	Zip:		Name:				Number:		
Key Contact:			Emai	l:								
Phone Number:			Fax	:		Is this p	roduct to be sl	hipped to cus	tomers on ic	e?	O Yes	No
		FOR (GENERIC DRUG PR	ODUCTS		Is this p	roduct to be sl	hipped to cus	tomers on d	ry ice?	○ Yes	No
I. Orange Book Ra	ting:		II. Brand Name:									
III. Generic Equival	lent for Brand:					c. Special	regulations for	r this product	in certain st	ates?	○ *Yes	s No
		ADDITIO	NAL PRODUCT INF	ORMATION		Special i	returns require	ements for th	is product?		○ *Yes	_
		Level	How?		GTIN-14	7	•		•			
Serialized?	O Yes O No	Item	2D Linear	RFID		d. Store pi	roduct (unit of	sale) upright	?		○ Yes	No
	0 100 0 110	Case	2D Linear	=	50355150171106		product (unit	,			O Yes	_
		Pallet	2D Linear		70355150171100			,	3		O les	© NO
Is the Product						e. Shelf life	e:		Months			
	Direct Ship Ite	em	Direct and Drop Ship	Drop Ship	o only item (See new page 3.)		Initial shelf li		4			Months
a Legend Device?	○ Yes	○ No						•	umoromey.			
a State Control?	O Yes	O No			ITEM AN	D PACKING	INFORMATIC	ON				
ARCOS reportable		O No		Order Info	ormation			Dimen	sions (US m	smts.)	Volume	
Co-Licensed?	O Yes	O No	Unit of Sale	What is the ND			Weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:
Repackaged?	O Yes	O No	Bottle	1 Box of 25 Via	•						<u> </u>	
Controlled Substar		O No	Box / Carton			Item:					0	
Schedule No.?	N	0 110	Ampule	(Wr	ite-in, e.g. 1 Box of 10 Vials)	Box/	4.00	5.045	0.000	5.045	00 70407	05 1.1.
	(incl. N for no	on-narcotic)	Glass	Minimum orde	r quantity? O Yes O No	Carton:	1.68	5.315	2.362	5.315	66.72467	25 vials
			Tube	K Vaa haw ma	my of which markeds tyme?	Casa	42.70	44.00	E E40	44.00	c02 00c0	200 vials
Hazardous Materia	al / Cytotoxic Agen	nt?	✓ Vial Liquid Sgl	ir res, now ma	ny of which package type?	Case:	13.78	11.22	5.512	11.22	693.8969	8x25 vials
	○ *Yes	No	Vial Liquid Multil		Eac	5 11 4	4000 50	47.044	40.747	00.07	70.450.40	70.01
Is Item O Unit	Dose O Unit o	of LISA	Vial Powder Sql		Inner / Carton	Pallet:	1029.56	47.244	42.717	39.37	79453.46	72 Shippers
If Unit Dose, is item b			Vial Powder Multi Other: Write In		Case		Case:		<u> </u>	<u> </u>	I.	
hospital scanning?	○ Yes	○ No	Other. Write in			UPC:	Carton:					
ls it reverse numbe		○ No	PHARMACY ORDE	R / BILL UNIT	Other Product Informati	on			COST INFO	RMATION		
is it reverse manibe	cica. Ores	O NO	Rec. sell unit to custo		Size/Strength/Form:		Regular Cos	t Per Unit of	I		Federal Exc	ise Tax Per
WHOLES	SALER USE ONL'	Υ:					_	e (\$)	Invoice Cos	st (WAC) (\$)	Unit of Sale	
Vendor #:			(Write-in, e.	a. 1 Vial)	Product Shape:		Jun	- \+/			J	
Whsl. Code #:			Rx billing unit to phar		Product Color:		1					
Fineline Code:			Each Gram	Millilite	Product Imprint:							
3040.					i roduct imprint.							



New Item	Promotion/Deal Open Stock	Post Launch Change	Date:	
INCAN ITCILI	FIUITIONION/Dear Open Stock	i ost Eddrich change		

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	AuroMedics Pl		RODUCT	INFORMATI	ON			SPECIAL	HANDLING A	AND STORA	GE REQUIR	EMENTS*			
Company Name:			NDA AN	IDA BLA Med Device 7	a. Temper	ture – Indicate the USP temperature range for this proc			roduct.						
		ber for NDA/ A	ANDA/ BLA, Med Device:					I. Freezer – between -25 and -10 C (-13° – 14° F)							
Rx Product / Proprietary Name: BUPIVACAINE HYDROCHLORIDE INJECTION, USP 0.75% (7.5 mg/ml						II. Cold – between 2 and 8 C (36° – 46° F)									
NDC:	55150-172-30		UPC:			III. Cool – between 8 and 15 C (46° – 59° F)									
	CVX Code:			MVX Code:			✓	✓ IV. Controlled Room – between 20 and 25 C (68° – 77° F)							
Description:	iption: BUPIVACAINE HYDROCHLO			ORIDE INJECTION, USP 0.75% (7.5 mg/mL) [30 mL Single Dose Vial]				allows for excursions between 15 and 30 C (59° – 86° F)							
							V. Avoid Excessive Heat – above 40 C (>104° F)								
Active ingredients:								VI. Other Ter	mperature Ra	inge Require	ment				
									(write in)						
URL for additional	product inform	ation:					VII. No Requirement								
Address:	6 Wheeling Road		Address 2:			b. Contact	b. Contact for temperature excursion questions:								
City:	Dayton, NJ 08810		State: Zip:		Zip:		Name:			Number:					
Key Contact:				Email:											
Phone Number:				Fax:			Is this p	roduct to be sl	hipped to cus	tomers on ic	e?	○ Yes	No		
		FOR (GENERIC DRUG PRODUCTS			Is this p	roduct to be sl	hipped to cus	tomers on d	ry ice?	O Yes	No			
I. Orange Book Ra	ting:		II. Brand	Name:											
III. Generic Equiva	lent for Brand:						c. Special	c. Special regulations for this product in certain states? \(\tau_{Yes} \)							
		ADDITIO	NAL PR	ODUCT INFO	RMATION		Special	returns require	ements for th	is product?		○ *Yes	s 🖲 No		
		Level	l I	How?		GTIN-14									
Serialized?	O Yes O No	Item	2D	2D Linear RFID			d. Store p	d. Store product (unit of sale) upright?					No		
		Case			50355150172301	Protect	Protect product (unit of sale) from				○ Yes	No			
		Pallet	t <u> </u>	Linear	RFID	70355150172305				=					
Is the Product	Direct Ship	ltom -	Direct one	Direct and Drop Ship Drop Ship only item (See new page 3.)		e. Shelf lif	e. Shelf life: Months					1			
			Direct and	a Drop Snip		only item (see new page s.)		Initial shelf li	fe at launch (if different):			Months		
a Legend Device?	O Yes		ITEM AND PACKING INFORMATIO						ON						
a State Control?	Yes							_	Dim	alama (IIO massita)					
ARCOS reportable Co-Licensed?	9 163		Unit of Sale	Order Information What is the NDC selling unit?		4	Weight Lbs.	<u>Dimen</u> Depth	nsions (US msmts.) Height Width:		Volume (Cube)	# Pieces:			
Repackaged?	○ Yes		Bottle		1 Box of 25 Vial	<u> </u>				1.0.9		(Cube)			
Controlled Substa	nce? O Yes		Box /	Carton	1 DOX OI 25 VIAI	3	Item:					0			
	N Yes	S	Ampu	ıle	(Writ	te-in, e.g. 1 Box of 10 Vials)	Box/								
		non-narcotic)	Glass	ľ	Minimum orde		Carton:	3.44	6.693	3.15	6.693	141.1082	25 Vials		
	•	•	Tube				C	40.40	44470	4 224	44.470	000 005	100 vials		
Hazardous Materia	al / Cytotoxic Ag	jent?		iquiu ogi	if Yes, now mai	ny of which package type?	Case:	16.49	14.173	4.331	14.173	869.985	2x2x25		
	○ *Ye	es 💿 No		iquid Multil		Eac	Dallati	020.02	47.044	45 470	20.27	0.4577.75	40 Chinner		
Is Item O Unit	Dose O Uni	it of Use		owder Sal owder Multi		Inner / Carton	Pallet:	829.02	47.244	45.472	39.37	843/1./3	48 Shippers		
	bar coded to unit dose for		Other: Write In	Case		UPC:	Case:								
hospital scanning?	○ Yes	s O No					UPC:	Carton:							
Is it reverse numbered? ○ Yes ○ No			PHARMACY ORDER / BILL UNIT Other Product Informatio			tion	on			COST INFORMATION					
	Rec. sell unit to customer?		er?	Size/Strength/Form:		Regular Cost Per Unit of		Invoice Cost (WAC) (\$)		Federal Excise Tax Per					
WHOLES						Sale	e (\$)		σ. (11ΛΟ) (Φ)	Unit of Sale)				
Vendor #:			(Write-in, e.g. 1 Vial)		Product Shape:										
Whsl. Code #:				g unit to pharm											
Fineline Code:	Each	Gram	Millilite	Product Imprint:											