

Version 2020						Introduction	n Type:	New Item			Final Version			Date:	14.JAN	N.2021
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	AuroMedics Pharma LLC ANDA Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/AN	DA/BLA (drug); PMA/510	)(k)(med devid	;e):	210	0321				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
DUNS:	968961354										Store at 20° to 25°C (68° to 77°F). [See USP					
Proprietary Name (If Applicable) a	and Established Name: Dexmedetomidine HCl in 0.9% Sodium Chloride Injection 55150-296-10 Unit of Use NDC: 55150-296-01				1100	2554502	2064.04	(write in)				Controlled Room Temperature]. Do not freeze. Discard unused portion.				
Selling Unit NDC: UDI	55150-296-10         Unit of Use NDC:         55150-296-01         UPC:         355150296101           CVX Code:         MVX Code:					296101		Notes			Do not freez	e. Discard ur	used portion.			
Description:	Dexmedetomidine HCl in 0.9% Sodium Chloride Injection 200 mcg per 50 mL (4 mcg/mL) - 10 Infusion Bags							la thia ar	aduatta ha ahinnaa				No			
Description:	Description. Description:						Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No									
Active Ingredient(s): Dexmedetomidine HCI										.,						
									b. Contact fo		ture excursion qu	estions:	-			
URL for Additional Product Inform Address:	nation: 279 Princeton-Hightstow	in Road			1	Address 2:	-			Name: Number:			Steve Lucas 732-823-412			
City:	East Windsor	TI KUdu			State:	NJ	Zip:	08520	Group E-mail:					obindousa.co	m	
Key Contact:					Email:											
Phone Number:	888-238-7880				Fax:	x: 732-355-9449			c. Special regulations for product in any states? No							
Product Therapeutic Classificatio	n: alpha	a2-adrenergic a	gonist							Special r	eturns requirement	s for this product?			No	
			ORMATION			PRODUC	TDESCO				( l - ) i - h - ( - )				N	
	ADDITIONAL F	RODUCTINF				PRODUC	I DESCRI	IPTION INFORMATION	d. Store proc	-	of sale) upright?				No	
The product is? a legend device?	No		Is the Product Is the Product	Direct-Ship C Neither	only		1	10 x 50 mL Single Dose	e. Shelf life:	Protect	product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #	No		Orphan Drug Status	Neither		Size:		Flexible Containers	e. Shen me.	Initial sh	elf life at launch (	if different):			24	Months
a product kit?	No		pg			Strength:		200 mcg per 50 mL				,				
if yes, list NDCs of			FDA Approval Status			Strength.		(4 mcg/mL)				ORDER INFORM	MATION			
component parts						Dosage Fo	orm:	Liquid		11-14-44			What is the	NDC selling		
reverse numbered? co-licensed?	No No		Allergens Present							Unit of S	Bottle		1 case of 10		unit?	
latex-free?	Yes		Allergens Fresent			Desident O		Infusion Bag			Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?	Yes					Product SI	nape:				Ampule			0	,	
correctional institution block?	No					Product C	olor:				Glass		Minimum o	rder quantity	?	Yes
opioid? Cannabinoid?	No		Country of Origin	India							Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for bospital		Country of Origin	mula		Product In	nprint:				Vial Liquid Sgl		If Yes, how	many of wh	ch package t	vne?
scanning?			Is this product covered u	nder the							Vial Powder Sql			Each	en puenage i	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (7	AA)?							Vial Power Multi			Inner/Cartor	/Pack	
										x	Other: Write In		1	Case		
			FOR GENERIC DRUG PR	ODUCTS					_		Infusion Bag					
					Auth	orized Generic	*If Autho	prized Generic, other section			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP			7				e not applicable	Rec. sell uni	t to custor				nit to pharm	acv.	
II. Generic Equivalent to What Bra		edex								1 case		1	x	Each		
									(Write-in, e.g	g. 1 Vial)		-		Gram		
	Ľ	DRUG SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION									Milliliter		
Does supplier meet DSCSA defini	tion of manufacturer?		Yes	GL	N:						ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No													
If yes, select exemption:											Weight Lbs.	Dimensi	ions (US msn	nts.)	Volume	# Pieces:
Other exemption - Write in:											weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?			No		es, was origied of the sect from mfr?	nal product purc	hased		Item/Each:		2.972	12.4	8.465	6.89	723.21574	10
Is product sold by manufacturer's Has FDA granted waiver/exception		?	No No	_		cumentation from	m FDA.		Box/Carton/	Bundle/						
		·		,					Inner Pack:	Duniano,						
		GTIN	AND HIBCC PRODUCT I	FORMATION					Case:		2.972	12.4	8.465	6.89	723.21574	1
											2.072	12.4	0.400	0.00	120.21014	
Saleable Unit of Measure	Quan	ntity IO	HIBCC		GTIN-	14 150296106	т	Unit of Use GTIN-14	Pallet:		365.918	48	40	53.23	102201.6	112
Box/Carton/Bundle/Inner Pack		10			50355	130290100	+									
X Case		1				150296106	1			COS	T INFORMATION			WHOLESAL	ER USE ONL	Y:
Pallet	1	12			70355	150296100										
	┥ ┝━				-		4		Regular Cos			C 400.00	Vendor #:	4.		
	┥ ┝━				┥ ┝──		4		Invoice Cost	(WAC) (\$)	1	\$ 430.00	Whsl. Code Fineline Co			
	1 -						1		As of date:							
													1	<u> </u>		
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza			RT, LABEL AND PHOTO OF	PRODUCT PACH							
*Please provide any additional inf	ormation on page 2.	<u> </u>				See new p. 3 f	or Design	ated Drop Ship Only.		Signatur	e:			Aravinda	Kumar A.	

Version 2020 For Designa	ated Drop Ship Only Products, Please Use Page 3
MATERIAL HA	AZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard
c. Contact Hazard?     d. Does this product require special clean-up instructions?     (If yes, attach SDS with special instructions.)     e. Does the product contain DEHP?     No     Is this product regulated for shipment by DOT?     (If yes, answer a-e below and provide SDS)     a. UN/Identification Number     b. Proper Shipping Name     c. DOT Hazard Class	Aerosol Class; Identify NFPA Storage Level:  Is the product a NIOSH hazardous drug? If yes, indicate which:  Hazardous Waste Identification  EPA Hazardous Waste Code: Waste Code: Waste Characteristics
d. Packing Group	
e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Desting Crause	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         If Yes, is it managed with a pharmacy registry?       Website URL:
d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Is this a reportable <u>quantity?</u> RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS:     No       REMS regram Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     PCPDP#:       by Supplier:     NPI #:
SP#	Registry:     Phone:
ADD'L STORAGE INFORMATION	Comments
Is the Product       Controlled Substance?       No       Controlled Substance Code         Controlled Substance?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:       If         Schedule No.       Is it a scheduled listed chemical product?:       No         CLASS OF TRADE RESTRICTION:         No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices         Yes       Restricted to retail pharmacy only:       No         Restricted to hospital, clinics, and physician offices only:       No	RETURN INSTRUCTIONS         Contact tel. # if product received damaged:       888-238-7880         Is product returnable for credit:       Yes         URL/Link to returns policy:       http://auromedics.com/policies/return-policy/         Special regulations or returns requirements for this product in certain states?       poduct in certain states?
Restricted from US territories? (explain in comments)     No       Comments:	If so, which states? Other requirements? Comments?
MISCELLANE	EOUS NOTES and/or Image of Product Barcode:



Version 2020 FOR DESIGNA	ATED DROP SHIP PRODUCT ONLY - if no	ot a designated drop ship, do not complete.	
Order Method for Designated Drop S	Ship Product	Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	nber:	Purchase order daily receipt cut off time by supplier         Cut off time:         Shipping lead time of PO:         Hours       Days         Ships same day for next day receipt:         Ships for second day receipt:         Ships regular ground for 3-10 days receipt:	
Expedited Freight Charges or Other Designa	ated Drop Ship Fees:	Overnight and Priority Overnight PO Processing	
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:		Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday	
		Priority Overnight receipt available:	
Class of Trade Restriction	n:	PO Receipt Cut off time:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	ics and physician offices	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:       Phone #:         Fax:       EDI:       Fax #:         Overnight Fees apply:       Other fees apply:       Other fees apply:	
Other Data Information Required to	Process PO:	Return Instructions	
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?	
Miscellaneous Notes:			
		ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?	



Version 2020					Introductio	n Type:	New Item		Fi	nal Version			Date:	14.JAI	N.2021
		PRODUCT INF	ORMATION							SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:						a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN	DA/BLA (drug); PMA/510(I	k)(med device):	210	0321				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
DUNS:	968961354							Other Temperature Range Requirement				Store at 20° to 25°C (68° to 77°F). [See USP			
Proprietary Name (If Applicable) a Selling Unit NDC:	) and Established Name: Dexmedetomidine HCl in 0.9% Sodium Chloride Injection 55150-297-10 Unit of Use NDC: 55150-297-01				1 UPC:	355150	207109		(write Notes	in)		Controlled Room Temperature]. Do not freeze. Discard unused portion.			
UDI	33130-237-10	CVX Code		33130-231-0	MVX Code:	333130	237100		NOICES			Do not neez	e. Discaru ui	useu portion.	
Description:	Dexmedetomidine HCl in (	0.9% Sodium Chloride Injection 40		mca/ml.) - 10				Is this product to be shipped to customers on ice? No							
									to customers on d			No	-		
Active Ingredient(s): Dexmedetomidine HCI													-		
URL for Additional Product Inform	nation.							b. Contact for		e excursion que	estions:	Steve Lucas			
Address:	279 Princeton-Hightstown	Road			Address 2:				Name: Number:			732-823-412			
City:	East Windsor			State:	NJ Zip: 08520			Group E-mail:			slucas@aurobindousa.com				
Key Contact:				Email:											
Phone Number:	888-238-7880	- decouverie - encolet		Fax:	732-355-9449	732-355-9449			-	product in any				No	-
Product Therapeutic Classificatio	n: alpha2	-adrenergic agonist		]					Special retu	irns requirement	s for this product?			No	-
	ADDITIONAL PR	ODUCT INFORMATION			PRODUC	T DESCR	IPTION INFORMATION	d. Store prod	luct (unit of s	ale) upright?				No	
The product is?		Is the Product	Direct-Ship C	nlv						duct (unit of sa	ale) from light?			No	-
a legend device?	No	Is the Product	Neither	,	Size:		10 x 100 mL Single Dose	e. Shelf life:			,			24	Months
if yes, enter class #		Orphan Drug Sta	tus		5ize.		Flexible Containers		Initial shelf	life at launch (i	if different):				Months
a product kit?	No				Strength:		400 mcg per 100 mL (4 mcg/mL)								
if yes, list NDCs of component parts		FDA Approval St	atus				Liquid				ORDER INFORM	MATION			
reverse numbered?	No				Dosage Fo	orm:			Unit of Sale	9		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Presen	t						Bo	ottle		1 case of 10	-		
latex-free?	Yes				Product S	hape:	Infusion Bag			ox/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?	Yes									mpule lass		Minimum o	der quantity	12	Yes
opioid?	No				Product C	olor:				ube		Winning	der quantit		163
Cannabinoid?	No	Country of Origin	India		Product In	nnrint			Vi	al Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for hospital				rioductii	nprint.				al Liquid Multi		If Yes, how	-	ch package	type?
scanning?		Is this product cov Trade Agreements								al Powder Sql al Power Multi			Each Inner/Cartor	/Deel/	
If Unit Dose, indicate NDC here:		ndde Agreementa								ther: Write In		1	Case	Pack	
		FOR GENERIC DRU	JG PRODUCTS					<u>•</u> ]		fusion Bag		1			
								<b></b>		-					
				Auth	orized Generic		orized Generic, other section re not applicable				ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP Dropped	ev.				neius ai		Rec. sell unit		?	1	Rx billing u		acy:	
II. Generic Equivalent to What Bra	and?: Preced	ex						(Write-in, e.g.	1 case		1	x	Each Gram		
	DR	UG SUPPLY CHAIN SECURITY	ACT (DSCSA) INFOR	RMATION				(					Milliliter		
										1751	I AND PACKING I				
Does supplier meet DSCSA defini Is product exempt from DSCSA?	tion of manufacturer?	Yes	GL	N:						IIEM	I AND PACKING I	NFORMATIO	N		
If yes, select exemption:								1			Dimensi	ions (US msn	nts.)	Volume	
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?		No			nal product pure	chased		Item/Each:		4.073	12.4	8.465	6.89	723.21574	10
Is product sold by manufacturer's		No		ect from mfr?							.2	0.100	0.00	120.21011	10
Has FDA granted waiver/exception	n/exemption for product?	No	If y	es, attach do	cumentation fro	m FDA.		Box/Carton/B Inner Pack:	Bundle/						
		GTIN AND HIBCC PROD	UCT INFORMATION					Case:		4.070	40.4	0.405	0.00	700 04574	
										4.073	12.4	8.465	6.89	723.21574	1
Saleable Unit of Measure	Quantit			GTIN-	14	-	Unit of Use GTIN-14	Pallet:		489.212	48	40	53.23	102201.6	112
X Item/Each Box/Carton/Bundle/Inner Pack	10			50355	0150297103	-									
Case	1			50355	150297103	1			COST II	NFORMATION			WHOLESAL	ER USE ONL	Y:
Pallet	112	2		70355	5150297107										
	┥ ┝━━					_		Regular Cost				Vendor #:			
	┥ ┝━━					-		Invoice Cost	(WAC) (\$)		\$ 800.00	Whsl. Code Fineline Co			
	1 -					1		As of date:							
Ц	-					-						1			
		Attach copy of SAFE	TY DATA SHEET (SD	S) or non haza			RT, LABEL AND PHOTO OF	PRODUCT PACK		BARCODE.					
*Please provide any additional inf	ormation on page 2.				See new p. 3 f	for Desigr	nated Drop Ship Only.		Signature:				Aravinda	Kumar A.	

Version 2020 For Desig	nated Drop Ship Only Products, Please Use Page 3
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	SDS Hazard Classification         Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard
c. Contact Hazard?     No     d. Does this product require special clean-up instructions?     (If yes, attach SDS with special instructions.)     e. Does the product contain DEHP?     No     Is this product regulated for shipment by DOT?     (If yes, answer a-e below and provide SDS)     a. UN/Identification Number     b. Proper Shipping Name     c. DOT Hazard Class	Aerosol Class; Identify NFPA Storage Level:  Is the product a NIOSH hazardous drug? If yes, indicate which:  Hazardous Waste Identification  EPA Hazardous Waste Code: Waste Characteristics
d. Packing Group e. Inhalation Hazard? No	
E. Illinaadol (12240)     Stris product regulated for shipment by IATA?     No     (if yes, answer a-e below and provide SDS)     a. UN/Identification Number     b. Proper Shipping Name     c. DOT Hazard Class     d. Packing Group	REMS or REGISTRY RESTRICTIONS       Is there a REMS on this product?     No       If Yes, is it managed with a pharmacy registry?     No       Website URL:     Image: Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2"Col
e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Perovision (listed in Column 7 of 49 CFR 172.101); SP#	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Site Enrollment Number assigned     DEA #:       by Supplier:     NPI #:
5P#	Registry:
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Phone:
Is the Product         No         Controlled Substance Code           Controlled by State(s)?         No         Listed Chemical (List I or II)         No	Comments RETURN INSTRUCTIONS
ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 888-238-7880
	Is product returnable for credit: Yes
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-policy/
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this
Restricted to hospital, clinics, and physician offices only:         No           Restricted from US territories? (explain in comments)         No	product in certain states?         If so, which states? Other requirements? Comments?
Comments:	
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



Version 2020 FOR DESIGNA	ATED DROP SHIP PRODUCT ONLY - if no	ot a designated drop ship, do not complete.	
Order Method for Designated Drop S	Ship Product	Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	nber:	Purchase order daily receipt cut off time by supplier         Cut off time:         Shipping lead time of PO:         Hours       Days         Ships same day for next day receipt:         Ships for second day receipt:         Ships regular ground for 3-10 days receipt:	
Expedited Freight Charges or Other Designa	ated Drop Ship Fees:	Overnight and Priority Overnight PO Processing	
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:		Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday	
		Priority Overnight receipt available:	
Class of Trade Restriction	n:	PO Receipt Cut off time:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	ics and physician offices	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:       Phone #:         Fax:       EDI:       Fax #:         Overnight Fees apply:       Other fees apply:       Other fees apply:	
Other Data Information Required to	Process PO:	Return Instructions	
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?	
Miscellaneous Notes:			
		ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?	