

Version 2021						Introduction 1	Гуре:	New Item		Final Version			Date:	9/30/2	/2022
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Eugia US LLC (f/	k/a AuroMedics Pharr	ma LLC)			Applica	tion:	ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for	this product			
Application Number for NDA/Al				20	0752					Temperature Range	Controlled Room	- between 20	and 25 C (68	3° – 77° F)	
Medical Device Class, if applica		in do ro(it)(inioù do rie							1	Tomporataro riango			(,	
DUNS:	968961354								1	Other Temperature Range F	equirement	Store at 20°	to 25°C (68°	to 77°F) [see I	LISP
Proprietary Name (If Applicable)		ne. Devra	zoxane for Injection, 500 mg						ī	(write in)	equirement	Controlled R			001
Selling Unit NDC:	55150-437-01	arric.	Unit of Use NDC:		55150-435-01	UPC:	35515043	7016		Notes					
UDI			CVX Code:			MVX Code:	00010010								
									:						
Description:	Injection, USP	Injection 500 mg per v	vial and 0.167M (M/6) Sodiur	n Lactate						Is this product to be shipped				No	l .
Andrea Income diagram	injection, USP	D								Is this product to be shipped	to customers on	dry ice?		No	1
Active Ingredient(s):		Dexrazoxane							h Camera 6a		-41				
URL for Additional Product Infor	mation:	eugiaus.com							b. Contact to	r temperature excursion que Name:	stions:	Kevin Cagne	atti		
Address:	279 Princeton-Hig				1	Address 2:	1		1	Number:		732.839.940			
City:	East Windsor	ginotowii itoaa			State:	NJ	Zip: 0	8520		Group E-mail:			EugiaUS.c	om	
Key Contact:	Last Willasor				Email:	140	Lip. 0	5020		Group E man.		Keagnettie	y Lugia OJ.C	OIII	
Phone Number:	888-238-7880				Fax:	732-355-9449			c. Special red	gulations for product in any	states?			No	i
Product Therapeutic Classification					-				or openiar res	Special returns requirement				No	i
Trouble Thorapound Glacomount	•									opoolal rotarrio roquiroriioni	o tor uno product.			. 10	
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT	DESCRIPTI	ON INFORMATION	d Store prod	uct (unit of sale) upright?				Yes	i
				Direct-Ship (Omle .				ai otoro proc						i
The product is?			Is the Product	Neither	Jrily		0			Protect product (unit of sa	le) from light?			Yes	
a legend device?		No	Is the Product	Neithei		Size:	Co	mbi Pack	e. Shelf life:	halfal ab alf life at lasses by				24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				500) mg per vial and		Initial shelf life at launch (i	r amerent):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:		67M (M/6)			ORDER INFOR	MATION			
component parts			FDA Approvai Status				1.46	ophilized Vial + Diluent			ORDER IN OR	WATION			
reverse numbered?		No				Dosage Forn	m: Ly	prillized viai + Diluerit		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		55150-437-0		uiii.	
latex-free?		Yes	Allergens i resent				Via	l Pack		x Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Sha	ipe:	. r doit		Ampule		(**************************************	g. 1 Dox 01 1	o vidio,	
correctional institution block?	>	No								Glass		Minimum o	der quantity	<i>i</i> ?	
opioid?		No				Product Cole	or:			Tube			uo. quu,		
Cannabinoid?		No	Country of Origin	India						Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		, ,			Product Imp	rint:			Vial Liquid Multi		If Yes, how	many of whi	ich package ty	ype?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (AA)?	No					Vial Power Multi			Inner/Cartor	n/Pack	
			_							Other: Write In		1	Case		
			FOR GENERIC DRUG PR	ODUCTS											
												_			
					Au	thorized Generic		zed Generic, other		PH	ARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AP						section fie	lds are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Br	rand?:	Zinecard®							Combipaci	with Lyophilized Vial and		x	Each	,	
									(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPPL	LY CHAIN SECURITY ACT (DSCSA) INFO	RMATION							x	Milliliter		
				_											
Does supplier meet DSCSA defin		rer?	Yes		GLN:					ITEM	AND PACKING	INFORMATIO	1		
Is product exempt from DSCSA?	,		No												
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msn			Saleable #
Other exemption - Write in:									I	Troigin LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or				Item/Each:	0.3829	3.543	1.732	3.149	19.32	1
Is product sold by manufacturer'			No	-	purchased di				D /2						
Has FDA granted waiver/exception		roduct?	No		Provide source	e manufacturer fo	or repackag	ed product	Box/Carton/E	Bundle/				0	
If yes, attach documentation fro	om FDA.								Inner Pack:						
		CTI	N AND HIBCC PRODUCT II	JEORMATION					Case:	20.502	14.566	10.826	6.889	1086.3369	48
		GII	N AND HIBCC PRODUCT II	NFORWATION					Pallet:			_			
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTII	N-14		nit of Use GTIN-14	railet.	Air: 1157.42	48	40	44.881	86171.52	2592
X Item/Each	•	1	TIBOO			55150437016	1	III. 01 036 G 1 IIN-14							
Box/Carton/Bundle/Inner Pack					003.	30.00707070				COST INFORMATION			WHOLESAL	ER USE ONLY	Υ:
X Case		48			503	55150437011									
x Pallet		2592				55150437015			Regular			Vendor #:			
		2002			100.				Invoice Cost	(WAC) (\$)	\$548.51	Whsl. Code	#:		
										· -/ \ */	φο 10.01	Fineline Co			
					_				1.1						
									As of date:	10/1/2022					
							-		As of date:	10/1/2022					
									As of date:	10/1/2022					
			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non hazal	rd letter, PACKAGE	INSERT, L	ABEL AND PHOTO OF P							



Version 2021

For Designated 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?	SDS Hazard Classification
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	X Organic Corrosive Inorganic Oxidizer Steroid/Androgen Corrosive
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?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:
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	Is the product a NIOSH hazardous drug? If yes, indicate which:
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: Phone: DEA #: NCPDP#: NCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No
	Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION	Comments
Is the Product Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes
	URL/Link to returns policy: https://eugiaus.com/policies/return-policy/
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		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:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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 2021						Introduction	ype.	New Item		Final Version	51 11 10 A 11 15 OF 6		Date:	9/30/	2022
			PRODUCT INFORMA	IION							DLING AND STOP				
Company Name:		k/a AuroMedics Pharr				Applica	tion:	ANDA	a. Temperatu	re - Indicate the USP temper					
Application Number for NDA/AN		MA/510(k)(med devi	ce):	20	00752					Temperature Range	Controlled Room	- between 20	and 25 C (68	3° – 77° F)	
Medical Device Class, if applica					_				l I						
DUNS:	968961354									Other Temperature Range	Requirement			to 77°F) [see	USP
Proprietary Name (If Applicable) a Selling Unit NDC:	55150-434-01	ame: Dexra	zoxane for Injection, 250 mg Unit of Use NDC:		55150-432-01	UPC:	05545	-0.10.101.5	-	(write in) Notes		Controlled R	Room Temper	aturej.	
Selling Unit NDC:	55150-434-01		CVX Code:		55150-432-01	MVX Code:	35515	50434015	-	Notes					
02.						MITA COUC.			1						
Description:	Dexrazoxane for	Injection 250 mg per	vial and 0.167M (M/6) Sodiur	n Lactate Injec	tion, USP					Is this product to be shippe				No	-
Active Ingredient(s):		Dexrazoxane							-	Is this product to be shipped	to customers on o	iry ice?		No]
Active ingredient(s):		Dexrazoxane							h Contact fo	r temperature excursion qu	actions:				
URL for Additional Product Inforr	nation:	eugiaus.com							b. Contact to	Name:	estions.	Kevin Cagne	etti		
Address:	279 Princeton-Hi					Address 2:			1	Number:		732.839.940			
City:	East Windsor				State:	NJ	Zip:	08520		Group E-mail:		kcagnetti(@EugiaUS.c	om	
Key Contact:					Email:										
Phone Number:	888-238-7880	1			Fax:	732-355-9449			c. Special reg	julations for product in any				No	
Product Therapeutic Classification	on:									Special returns requirement	s for this product?			No	
		IONAL DDGDUGG	FORMATION			DRABHAS	DECO	NETION INFORMATION						- 10	1
	ADDIT	IONAL PRODUCT IN				PRODUCT	DESCR	RIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				Yes	_
The product is?			Is the Product	Direct-Ship	Only					Protect product (unit of sa	le) from light?			Yes	
a legend device?		No	Is the Product	Neither		Size:		Combi Pack	e. Shelf life:					24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status					250 mg per vial and		Initial shelf life at launch (t different):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:		0.167M (M/6)			ORDER INFORM	MATION			
component parts			. Dririppioral GlataG			1		Lyophilized Vial + Diluent							
reverse numbered?		No				Dosage Form	m:	,		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		55150-434-0			
latex-free?		Yes				Product Sha	ipe:	Vial Pack		x Box/Carton		(Write-in, e.	e.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes					•			Ampule				_	
correctional institution block? opioid?		No				Product Col	or:			Glass Tube		Minimum o	order quantity	17	
Cannabinoid?		No No	Country of Origin	India						Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	country or origin	maid		Product Imp	rint:			Vial Liquid Multi		If Yes, how	many of wh	ich package t	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sql			Each		71
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	ΓAA)?	No					Vial Power Multi			Inner/Cartor	n/Pack	
]	Other: Write In		1	Case			
			FOR GENERIC DRUG PR	ODUCTS											
												/ Bu 100			
				_	Au	thorized Generic		thorized Generic, other on fields are not applicable			ARMACY ORDER				
I. Orange Book Rating:	AP	T 10					Section	in helds are not applicable		to customer?	1		init to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Zinecard®								with Lyophilized Vial and		X	Each Gram		
		DRUG SUPPI	Y CHAIN SECURITY ACT (DSCSA) INFO	RMATION				(Write-in, e.g	. I VIAI)		x	Milliliter		
		2.1.00 00. 1 1		<i>50007.</i> , 0											
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes		GLN:					ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:				11	\$87-1-L-1-1	Dimens	ions (US msn	mts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product			Item/Each:	0.3306	2.952	1,456	2.755	11.84	1
Is product sold by manufacturer's			No	_		rect from mfr?						1.100			
Has FDA granted waiver/exception		roauct?	No		Provide sour	ce manufacturer fo	or repac	ckaged product	Box/Carton/E Inner Pack:	sunaie/				0	
If yes, attach documentation fro	III FUA.								Case:						
		GT	N AND HIBCC PRODUCT II	NFORM <u>ATION</u>					1	18.07791	12.204	9.251	6.102	688.91	48
									Pallet:	Air: 1334.679	48	40	46.062	88439.04	3456
Saleable Unit of Measure	5	Saleable Quantity	HIBCC			N-14		Unit of Use GTIN-14		AIT: 1334.679	48	40	46.062	00439.04	3456
X Item/Each		1			003	55150434015									
Box/Carton/Bundle/Inner Pack		40				FF4F0404040				COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		48				55150434010 55150434014	-		Boguiter			Vander #			
X Pallet		3456			/03	JJ 130434014	-		Regular Invoice Cost	(WAC) (\$)	\$274.26	Vendor #: Whsl. Code	a #-		
									invoice cost	(**AO) (#)	φ∠14.20	Fineline Co			
									As of date:	10/1/2022		1			
									<u> </u>			⊥			
			Attach copy of SAFETY DA	TA SHEET (S	DS) or non haza			RT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE.					
*Please provide any additional in	formation on nage	2				See new n 3 for	Design	nated Dron Shin Only		Signature:			D. Venkata Si	urender Reddy	V



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For Designated 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?	SDS Hazard Classification
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	X Organic Corrosive Inorganic Oxidizer Steroid/Androgen Corrosive
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?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:
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	Is the product a NIOSH hazardous drug? If yes, indicate which:
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: Phone: DEA #: NCPDP#: NCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No
	Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION	Comments
Is the Product Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes
	URL/Link to returns policy: https://eugiaus.com/policies/return-policy/
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		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:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?