

Version 2024						Introduction ²	Туре:	Post Launch Change]	Final Version			Date:	20.0	8.24
			PRODUCT INFORMAT	TION						SPECIAL HAND	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Eugia US LLC					Applica	tion:	ANDA	a. Temperature	- Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/AN	DA/BLA; PMA/510	0(k): 203082									Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat															
DUNS:	968961354									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		lame: Lidocai	ne Hydrochloride Injection,	USP						(write in)					
Selling Unit NDC: UDI	55150-161-02		Unit of Use NDC: CVX Code:		55150-161-02	UPC: MVX Code:	35515016	51027		Notes					
						WIVA Code:									
Description:	Lidocaine Hydroc	chloride Injection USP,	1% 20mg/2mL (10mg/mL)	[Single Dose Vi	als]					Is this product to be shipped				No	
Active Ingredient(s):		Lidocaine Hydrochlo	rido LICD							Is this product to be shipped	to customers on d	ry ice?		No	
Active ingredient(s):		Lidocaine Hydrochio	ilide USP						h Contact for	temperature excursion que	astions:				
URL for Additional Product Inforn	nation:	https://eugiaus.c	com/products/? sft alp	phabet=m						Name:	cottons.	Eugia US Cu	ustomer Serv	ce	
Address:	279 Princeton-Hig		,			Address 2:			1	Number:		888-238-788			
City:	East Windsor				State:	NJ	Zip:	08520		Group E-mail:		Customers	Service@Eu	giaUS.com	
Key Contact:					Email:										
Phone Number:	888-238-7880				Fax:	732-355-9449				lations for product in any				No	
Product Therapeutic Classification	n:	ANESTHETIC								Special returns requirement	s for this product?			No	
	ADDITI	IONAL PRODUCT INF	ODMATION			PRODUCT	DESCRIPT	ION INFORMATION							
	ADDITI	IONAL PRODUCT INF				PRODUCTI	DESCRIPT	ION INFORMATION	1	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only					Protect product (unit of sa	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit of Use		Size:	10	x 2 mL Vials	e. Shelf life:	Initial shelf life at launch (if different).			36	Months Months
a product kit?		No	Orphan Drug Status				20	mg/2 mL(10 mg/mL)		initial shell life at launch (ir different):				WORTHS
if yes, list NDCs of		IVO	FDA Approval Status			Strength:	20	mg/2 mc(10 mg/mc)			ORDER INFORM	ATION			
component parts						Danama Fam	Lic	quid							
reverse numbered?		No				Dosage For	m:		II .	Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 Box of 10 \			
latex-free?		Yes				Product Sha	ape: Vi	al Pack		x Box/Carton		(Write-in, e.	g. 1 Box of 1) Vials)	
preservative-free?		Yes								Ampule				•	V
correctional institution block? opioid?		No No				Product Col	or:			Glass Tube		Minimum o	rder quantity	· ·	Yes
Cannabinoid?		No	Country of Origin	India						Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		Country or origin			Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sql			Each		•
If Unit Dose, indicate NDC here:			Trade Agreements Act (7	ΓAA)?	No					Vial Power Multi			Inner/Carton	/Pack	
]	Other: Write In		1	Case		
			FOR GENERIC DRUG PRO	DDUCTS											
							*16 A	i1 Oii		DU	ARMACY ORDER	/ DILL LINET			
				_	Aut	thorized Generic		rized Generic, other elds are not applicable	5 "		ARMACT ORDER				
I. Orange Book Rating:	AP	Videosino@ (lideosin	ie HCI) Injection – Methyl Pa	araban Fras /M	DE) 40/		3000001111	cias are not applicable	Rec. sell unit t		1	Rx billing u		acy:	
II. Generic Equivalent to What Bra	ina ?:	Aylocalne® (lidocaln	ie nci) injection – Methyl Pa	araben Free (ivi	PF) 176				(Write-in, e.g.	10 Vials		X	Each Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION				HCPCS J-Code				Milliliter		
			•	,											
Does supplier meet DSCSA defini	tion of manufactu	urer?	Yes		GLN:					ITEM	AND PACKING IN	FORMATION	l		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:] [Weight Lbs.		ons (US msm			Saleable #
Other exemption - Write in:										rreigiit Lus.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		iginal product			Item/Each:	0.21	3.54	1.38	1.77	8.647	10
Is product sold by manufacturer's Has FDA granted waiver/exception			No		-	rect from mfr? ce manufacturer f			Box/Carton/Bu	ا ماله س					
If yes, attach documentation from		oroduct?			Provide source	ce manuracturer i	ог гераска	igea product	Inner Pack:	inale/					
ii yes, attaon accumentation not	III I DA.								Case:	00.007				4045.00	4000
		GTIN	AND HIBCC PRODUCT IN	IFORMATION					1	26.637	15.55	12	8.66	1615.96	1200
									Pallet:	1471.459	48	40	56.97	109382.4	64800
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	ι	Jnit of Use GTIN-14		1471.409	40	40	30.37	109302.4	04000
II		Quantity			0.55	F4F0404007	-								
x Item/Each Box/Carton/Bundle/Inner Pack		10			0038	55150161027				COST INFORMATION			NHOLESAL	R USE ONL	v
Box/Carton/Bundle/Inner Pack Case		1200			6034	55150161029				COST INFORMATION		\ \	MOLESAL	IN USE UNL	1.
x Case Pallet		64800				55150161029			Regular Cost			Vendor #:			
							1		Invoice Cost (\	WAC) (\$)	\$22.20	Whsl. Code	#:		
												Fineline Co	de:		
									As of date:	9/10/2024					
									11			1			
<u> </u>			Au	EA OLIEST (C.	0)	D10//10-	INIOEST :	ADEL AND SUCTO SE	DDODUOT SASSIS	OINO 1 DADOODE		<u> </u>			
*Place provide any additional inf	ormation on need		Attach copy of SAFETY DA	IA SHEET (SD	or non hazar			ABEL AND PHOTO OF	PRODUCT PACKA	Signature:		Г) Venkata Su	render Reddy	,



Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, c. Contact Hazard? No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned NCPDP#: Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry:

Registry Program Contact Name ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: Yes **CLASS OF TRADE RESTRICTION:** 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 Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments:



Version 2024

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time:							
b. Autofax Fax Number:								
c. Fax Fax Number:	Shipping lead time of PO: Hours Days							
d. Phone No.:								
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:							
Minimum Order Quantity:	Ships for second day receipt:							
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:							
Contracted 3PL company / contact #: Name: Phone:								
	Overwight and Brigaity Overwight DO Breezesing							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order:	PO Receipt cut off time:							
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday							
Comments:	Tuesday							
	Wednesday							
	Thursday							
	Friday Friday							
	Priority Overnight receipt available:							
Class of Trade Restriction:	PO Receipt Cut off time:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:							
Restricted to retail pharmacy only:	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only:	Phone:							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	EDI:							
	Overnight Fees apply:							
	Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date:	Contact # if product is received damaged:							
Physician Name:	Is product returnable for credit:							
Physician/Clinic Phone #	URL/Link to returns policy:							
Physician State License #								
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?							
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?							
	Is product order for restocking purposes?							
	To product for recomming parposes.							



Version 2024						Introduction ²	Туре:	Post Launch Change		Final Version			Date:	06.0	8.24
			PRODUCT INFORMAT	TION						SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Eugia US LLC					Applica	tion:	ANDA	a. Temperatur	e - Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/AN	DA/BLA; PMA/510	0(k): 203082									Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicat															
DUNS:	968961354									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		lame: Lidocai	ne Hydrochloride Injection,	USP						(write in)					
Selling Unit NDC: UDI	55150-162-05		Unit of Use NDC: CVX Code:		55150-162-05	UPC: MVX Code:	35515016	52055	-	Notes					
						MIVA Code:									
Description:	Lidocaine Hydroc	chloride Injection USP,	1% 50mg/5mL (10 mg/mL)	[Single Dose V	'ials]					Is this product to be shipped				No	
Active Ingredient(s):		Lidocaine Hydrochlo	rido LICD						-	Is this product to be shipped	to customers on d	Iry ice?		No	
Active ingredient(s):		Lidocaine Hydrochio	ilide USP						h Contact for	temperature excursion que	etione:				
URL for Additional Product Inforn	nation:	https://eugiaus.c	com/products/? sft alp	phabet=m					D. Comact for	Name:	ostions.	Eugia US C	ustomer Serv	ice	
Address:	279 Princeton-Hig		,			Address 2:				Number:		888-238-788			
City:	East Windsor				State:	NJ	Zip:	08520		Group E-mail:		Customer	Service@Eu	ugiaUS.com	
Key Contact:					Email:										
Phone Number:	888-238-7880				Fax:	732-355-9449			c. Special regu	lations for product in any				No	
Product Therapeutic Classification	n:	ANESTHETIC								Special returns requirement	s for this product?			No	
	ADDITI	IONAL PRODUCT INF	ODMATION			PRODUCT	DESCRIPT	ION INFORMATION	.						ı
	ADDITI	IONAL PRODUCT INF				PRODUCTI	DESCRIPT	ION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only					Protect product (unit of sa	ile) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit of Use		Size:	10	x 5 mL Vials	e. Shelf life:	Initial shelf life at launch (f difforant\:			36	Months Months
a product kit?		No	Orphan Drug Status				50	mg/5 mL(10 mg/mL)		initial shell life at launch (r amerent):				Wonths
if yes, list NDCs of		140	FDA Approval Status			Strength:	00	mg/o me(to mg/me)			ORDER INFORM	IATION			
component parts						Danama Fam	Lic	quid							
reverse numbered?		No				Dosage For	m:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 Box of 10			
latex-free?		Yes				Product Sha	ape: Vi	al Pack		x Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes								Ampule					V
correctional institution block? opioid?		No No				Product Col	or:			Glass Tube		wiinimum o	rder quantity	11	Yes
Cannabinoid?		No	Country of Origin	India						Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		Country or origin			Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sql		,	Each		•
If Unit Dose, indicate NDC here:			Trade Agreements Act (7	ΓAA)?	No					Vial Power Multi			Inner/Carton	/Pack	
]	Other: Write In		1	Case		
			FOR GENERIC DRUG PRO	DDUCTS											
						uhi 1	*16 A	i 1 Oi 11		DU	ARMACY ORDER	/ DILL LIMIT			
				_	Aut	thorized Generic		rized Generic, other elds are not applicable			ARMACT URDER				
I. Orange Book Rating:	AP	Videosino@ (lideosin	ie HCI) Injection – Methyl Pa	araban Fras /M	DE) 40/		3000001111	cias are not applicable	Rec. sell unit t		ı		nit to pharm	acy:	
II. Generic Equivalent to What Bra	ina ?:	Aylocalne® (lidocaln	ie nci) injection – Methyl Pa	araben Free (ivi	PF) 176				(Write-in, e.g.	10 Vials		X	Each Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION				HCPCS J-Cod				Milliliter		
			•	,											
Does supplier meet DSCSA defini	tion of manufactu	urer?	Yes		GLN:					ITEM	AND PACKING IN	IFORMATIO	١		
Is product exempt from DSCSA?			No											·	·
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msn	nts.)		Saleable #
Other exemption - Write in:										rreigiit Lus.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		iginal product			Item/Each:	0.45	5.12	2.05	1.97	20.677	10
Is product sold by manufacturer's Has FDA granted waiver/exception			No		-	rect from mfr? ce manufacturer f	or ronaci-	and product	Box/Carton/Bu	indlo/					
If yes, attach documentation from		oroduct?			Provide source	ce manuracturer i	ог гераска	igea product	Inner Pack:	indle/					
ii yes, attaon accumentation not	III I DA.								Case:	40.040	44.04	44.04		740.70	
		GTIN	AND HIBCC PRODUCT IN	IFORMATION						10.046	11.61	11.61	5.51	742.70	200
									Pallet:	1118.008	48	40	54.6	104832	21600
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	ι	Init of Use GTIN-14		1110.000	40	+0	54.0	104032	21000
II		Quantity			0.55		-								
x Item/Each Box/Carton/Bundle/Inner Pack		10			0035	55150162055				COST INFORMATION			NHOLESAL	ER USE ONL	٧٠
Box/Carton/Bundle/Inner Pack Case		200			5035	55150162050				COST INFORMATION			MICEESAL	LK USE UNL	.11.
x Case Pallet		21600				55150162054			Regular Cost			Vendor #:			
							1		Invoice Cost (WAC) (\$)	\$29.60	Whsl. Code	#:		
												Fineline Co	de:		
									As of date:	9/10/2024					
<u> </u>			Au	EA OLIEST (C.	0)	BAGKAS-	INIOEST :	ADEL AND SUCTO SE	DDODUCT DAG:::	OINO 1 DADOODE		l			
*Place provide any additional inf	ormation on need		Attach copy of SAFETY DA	IA SHEET (SD	or non hazar			ABEL AND PHOTO OF	PRODUCT PACKA	Signature:) Venkata Su	ırender Reddy	V



Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, c. Contact Hazard? No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned NCPDP#: Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry:

Registry Program Contact Name ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: Yes **CLASS OF TRADE RESTRICTION:** 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 Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments:



Version 2024

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time:							
b. Autofax Fax Number:								
c. Fax Fax Number:	Shipping lead time of PO: Hours Days							
d. Phone No.:								
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:							
Minimum Order Quantity:	Ships for second day receipt:							
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:							
Contracted 3PL company / contact #: Name: Phone:								
	Overwight and Brigaity Overwight DO Breezesing							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order:	PO Receipt cut off time:							
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday							
Comments:	Tuesday							
	Wednesday							
	Thursday							
	Friday Friday							
	Priority Overnight receipt available:							
Class of Trade Restriction:	PO Receipt Cut off time:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:							
Restricted to retail pharmacy only:	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only:	Phone:							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	EDI:							
	Overnight Fees apply:							
	Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date:	Contact # if product is received damaged:							
Physician Name:	Is product returnable for credit:							
Physician/Clinic Phone #	URL/Link to returns policy:							
Physician State License #								
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?							
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?							
	Is product order for restocking purposes?							
	To product for recomming parposes.							



Version 2024						Introduction ²	Гуре:	Post Launch Change		Final Version			Date:	06.0	8.24
			PRODUCT INFORMAT	ION						SPECIAL HAND	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Eugia US LLC					Applica	tion:	ANDA	a. Temperatur	e - Indicate the USP tempe	rature range for ti	nis product.			
Application Number for NDA/AN	IDA/BLA; PMA/51	0(k): 207182								Temperature Range	Controlled Room -		and 25 C (68	8° – 77° F)	
Medical Device Class, if applical															
DUNS:	968961354									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		lame: Lidocair	ne Hydrochloride Injection, I	USP						(write in)					
Selling Unit NDC: UDI	55150-251-10		Unit of Use NDC: CVX Code:		55150-251-10	UPC: MVX Code:	35515025	1100	-	Notes					
-			CVX Code:			MVX Code:			_						
Description:	Lidocaine HCI Inj	ection USP (MDV) 1%								Is this product to be shipped				No	
Active Ingredient(s):		Lidosoino Hudrooblo	ride USP 1% 100mg/10mL	(10ma/ml) Mi	Itinla Dasa Viale				-	Is this product to be shipped	to customers on d	ry ice?		No	
Active ingredient(s):		Lidocaine nydrochiol	ide USP 1% TOURIG/TOTIL	(TOTTIG/TITE) IVIL	illiple Dose viais	5			h Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform	nation:	https://eugiaus.c	om/products/? sft alp	habet=m						Name:	cotions.	Eugia US Cu	ustomer Serv	rice	
Address:	279 Princeton-Hi					Address 2:			-	Number:		888-238-788			
City:	East Windsor				State:	NJ	Zip: 0	8520		Group E-mail:		CustomerS	Service@Eu	ugiaUS.com	
Key Contact:					Email:										
Phone Number:	888-238-7880				Fax:	732-355-9449				lations for product in any				No	
Product Therapeutic Classificatio	n:	ANESTHETIC								Special returns requirement	s for this product?			No	
	ADDITI	IONAL PRODUCT INF	ODMATION			PRODUCT	DECEMBE	ON INFORMATION							
	ADDITI	IONAL PRODUCT INFO				PRODUCTI	DESCRIPTI	ION INFORMATION	- I I	ct (unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship	Only		0.5	40 1151		Protect product (unit of sa	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status			Size:	25	x 10 mL Vials	e. Shelf life:	Initial shelf life at launch (if different):			24	Months Months
a product kit?		No	Orphan Drug Status				10	0 mg/10 mL(10		initial shell life at launch (ii diliterent):				Wonths
if yes, list NDCs of		INO	FDA Approval Status			Strength:		1/mL)			ORDER INFORM	ATION			
component parts						Dosage For	Liq	uid							
reverse numbered?		No				Dosage For	m:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 Box of 25 \			
latex-free?		Yes				Product Sha	pe: Via	al Pack		x Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No								Ampule					V
correctional institution block? opioid?		No No				Product Col	or:			Glass Tube		Minimum or	rder quantity	y?	Yes
Cannabinoid?		No	Country of Origin	India						Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	140	Country or Origin	maid		Product Imp	orint:			Vial Liquid Multi		If Yes. how	many of wh	ich package	type?
hospital scanning?	and dood for		Is this product covered u	nder the						Vial Powder Sql			Each		77
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No					Vial Power Multi			Inner/Cartor	n/Pack	
									<u>] </u>	Other: Write In		1	Case		
		F	OR GENERIC DRUG PRO	DDUCTS											
										DU	ADMAGY ODDED	DILL LINET			
				_	Aut	thorized Generic		ized Generic, other elds are not applicable			ARMACY ORDER				
I. Orange Book Rating:	AP		1100 1 1 11 11				36CHOIT IIC	aus are not applicable	Rec. sell unit t		1	Rx billing u		acy:	
II. Generic Equivalent to What Bra	and?:	Xylocaine® (lidocaine	e HCl) Injection – 1% man	ufactured by Fi	resenius Kabi Us	SA			(Myste in a a	25 Vials		X	Each Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (OSCSA) INFO	RMATION				(Write-in, e.g. HCPCS J-Code				Milliliter		
		51100 0011 21	01111110200111111101 (2	, , , , , , , , , , , , , , , , , , ,					1101 00 0 000	u.	1		Williamo		
Does supplier meet DSCSA defini	ition of manufactu	urer?	Yes		GLN:					ITEM	AND PACKING IN	FORMATION	1		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					M/-1	Dimensio	ns (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product			Item/Each:	2.09	5.55	5.55	2.75	84.707	25
Is product sold by manufacturer's			No			rect from mfr?					0.00	0.00	20	0 0	
Has FDA granted waiver/exceptio		product?			Provide sour	ce manufacturer f	or repacka	ged product	Box/Carton/Bu	undle/					
If yes, attach documentation fro	m FDA.								Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION					Case.	18.46	11.81	11.81	6.29	877.30	200 vials
									Pallet:	1005 100			== 00	4000400	40000
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	U	Init of Use GTIN-14		1805.166	48	40	55.39	106348.8	19200
ll		Quantity					_								
x Item/Each		25			0035	55150251100				0007 111700111				ED 1105	
Box/Carton/Bundle/Inner Pack		200			500	E4E00E440E	-			COST INFORMATION		, V	WHOLESAL	ER USE ONL	.Υ:
X Case		200 19200				55150251105 55150251109	-		Regular Cost			Vendor #:			
x Pallet		19200			7035	00100201109	+		Invoice Cost (WAC) (\$)	\$64.97	vendor #: Whsl. Code	#-		
									invoice cost ((Ψ)	φυ4.97	Fineline Code			
									As of date:	9/10/2024		50			
	-														
*Places provide any additional inf			ttach copy of SAFETY DAT	TA SHEET (SD	S) or non hazar				PRODUCT PACKA	GING and BARCODE.					
						Soo now n 2 for				Clampture			1 Vankata Ci	render Redd	,



Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, c. Contact Hazard? No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned NCPDP#: Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry:

Registry Program Contact Name ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: Yes **CLASS OF TRADE RESTRICTION:** 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 Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments:



Version 2024

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time:							
b. Autofax Fax Number:								
c. Fax Fax Number:	Shipping lead time of PO: Hours Days							
d. Phone No.:								
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:							
Minimum Order Quantity:	Ships for second day receipt:							
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:							
Contracted 3PL company / contact #: Name: Phone:								
	Overwight and Brigaity Overwight DO Breezesing							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order:	PO Receipt cut off time:							
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday							
Comments:	Tuesday							
	Wednesday							
	Thursday							
	Friday Friday							
	Priority Overnight receipt available:							
Class of Trade Restriction:	PO Receipt Cut off time:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:							
Restricted to retail pharmacy only:	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only:	Phone:							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	EDI:							
	Overnight Fees apply:							
	Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date:	Contact # if product is received damaged:							
Physician Name:	Is product returnable for credit:							
Physician/Clinic Phone #	URL/Link to returns policy:							
Physician State License #								
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?							
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?							
	Is product order for restocking purposes?							
	To product for recomming parposes.							



Version 2024						Introduction 1	Гуре: Г	Post Launch Change		Final Version			Date:	06.08	8.24
			PRODUCT INFORMAT	TION						SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Eugia US LLC					Applica	tion:	ANDA	a. Temperature	- Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/AN	NDA/BLA; PMA/510	0(k): 203082	2								Controlled Room -		and 25 C (68	s° – 77° F)	
Medical Device Class, if applical															
DUNS:	968961354								C	ther Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		lame: Lidocai	ne Hydrochloride Injection,	USP						(write in)					
Selling Unit NDC: UDI	55150-163-30		Unit of Use NDC: CVX Code:		55150-163-30	UPC: MVX Code:	355150163	3304	- I	otes					
-						MIVA Code:									
Description:	Lidocaine Hydroc	chloride Injection, USP	1% 300mg/30mL (10mg/m	L) Single Dose	Vial					this product to be shipped				No	
Active Ingredient(s):		Lidocaine Hydrochlo	orido LICD						_ Is	this product to be shipped	to customers on d	Iry ice?		No	
Active ingredient(s):		Lidocaine Hydrochid	onde USP						h Contact for te	mperature excursion que	astions:				
URL for Additional Product Inform	mation:	https://eugiaus.c	com/products/? sft alp	phabet=m						ame:	cottons.	Eugia US Cı	ustomer Serv	ice	
Address:	279 Princeton-Hig					Address 2:			-	umber:		888-238-788			
City:	East Windsor				State:	NJ	Zip: 08	520	G	roup E-mail:		Customers	Service@Eu	giaUS.com	
Key Contact:					Email:										
Phone Number:	888-238-7880				Fax:	732-355-9449				tions for product in any				No	
Product Therapeutic Classificatio	on:	ANESTHETIC							S	pecial returns requirement	s for this product?			No	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION															
	ADDITI	ONAL PRODUCT INF				PRODUCTI	JESCRIPTIC	ON INFORMATION	- I	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only					rotect product (unit of sa	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit of Use		Size:	30 n	nL Single-Dose Vial	e. Shelf life:	itial shelf life at launch (if different):			36	Months Months
a product kit?		No	Orphan Drug Status				1%	300 mg/30 mL(10	"	intial shell life at launch (ir different):				Wonths
if yes, list NDCs of		IVO	FDA Approval Status			Strength:	mg/				ORDER INFORM	ATION			
component parts						Danama Fam	Liqu								
reverse numbered?		No				Dosage Fori	n:		U	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 Box of 1 V			
latex-free?		Yes				Product Sha	pe: Vial	Pack		x Box/Carton		(Write-in, e.	g. 1 Box of 1) Vials)	
preservative-free?		Yes							_	Ampule					V
correctional institution block? opioid?		No No				Product Col	or:			Glass Tube		Wilnimum o	rder quantity		Yes
Cannabinoid?		No	Country of Origin	India						Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	NO	Country of Origin	maia		Product Imp	rint:			Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?
hospital scanning?	ariit dooo toi		Is this product covered u	nder the						Vial Powder Sql			Each	pg	76
If Unit Dose, indicate NDC here:			Trade Agreements Act (No					Vial Power Multi			Inner/Carton	/Pack	
										Other: Write In		1	Case		
			FOR GENERIC DRUG PRO	DDUCTS											
										DIL	ARMACY ORDER	/ DULL LINUT			
				_	Au	thorized Generic		ed Generic, other ds are not applicable			ARMACY ORDER				
I. Orange Book Rating:	AP	V. 1 i @ //i-1 i	- HON Indication - Mathed D		DE) 40/ /ADD D	t \	Section nei	us are not applicable	Rec. sell unit to		1		nit to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Xylocalne® (ildocaln	ne HCI) Injection – Methyl Pa	araben Free (M	PF) 1% (APP P	narms)			(Write-in, e.g. 1	1 Vial		X	Each Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFO	RMATION				HCPCS J-Code:	viai)			Milliliter		
			,	,											
Does supplier meet DSCSA defini	ition of manufactu	urer?	Yes		GLN:					ITEM	AND PACKING IN	IFORMATION	l		
Is product exempt from DSCSA?			No							·					
If yes, select exemption:					GCP:					Weight Lbs.	Dimensio	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:										weight LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product			Item/Each:	0.16	1.57	2.09	3.15	10.336	1
Is product sold by manufacturer's			No			rect from mfr?			Box/Carton/Bun	اماله					
Has FDA granted waiver/exceptio If yes, attach documentation fro		product?			Provide sour	ce manufacturer f	or repackag	ed product	Inner Pack:	dle/ 4.13	10.08	8.9	3.78	339.111	24
ii yes, attacii documentation no	mir DA.								Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION						26.324	19.291	11.023	12.992	2762.68	144
									Pallet:	075 440	48	40	56.97	100202.4	4608
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTII	N-14	Un	nit of Use GTIN-14		875.412	40	40	50.97	109382.4	4000
		Quantity													
x Item/Each		1 24				55150163304 55150163305				COST INFORMATION			NUOL ESAL	R USE ONL	V
X Box/Carton/Bundle/Inner Pack X Case		144				55150163305 55150163309	+			COST INFORMATION		, ,	WHOLESALI	R USE UNL	1.
X Case X Pallet		4608				55150163309	+		Regular Cost			Vendor #:			
		.000					1		Invoice Cost (W	AC) (\$)	\$3.19	Whsl. Code	#:		
							1				\$3.10	Fineline Co			
									As of date:	9/10/2024					
									As of date:	9/10/2024					
			Attach copy of SAFETY DA				1								



Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, c. Contact Hazard? No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned NCPDP#: Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry:

Registry Program Contact Name ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: Yes **CLASS OF TRADE RESTRICTION:** 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 Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments:



Version 2024

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time:							
b. Autofax Fax Number:								
c. Fax Fax Number:	Shipping lead time of PO: Hours Days							
d. Phone No.:								
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:							
Minimum Order Quantity:	Ships for second day receipt:							
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:							
Contracted 3PL company / contact #: Name: Phone:								
	Overwight and Brigaity Overwight DO Breezesing							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order:	PO Receipt cut off time:							
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday							
Comments:	Tuesday							
	Wednesday							
	Thursday							
	Friday Friday							
	Priority Overnight receipt available:							
Class of Trade Restriction:	PO Receipt Cut off time:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:							
Restricted to retail pharmacy only:	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only:	Phone:							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	EDI:							
	Overnight Fees apply:							
	Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date:	Contact # if product is received damaged:							
Physician Name:	Is product returnable for credit:							
Physician/Clinic Phone #	URL/Link to returns policy:							
Physician State License #								
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?							
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?							
	Is product order for restocking purposes?							
	To product for recomming parposes.							



Version 2024						Introduction ²	Гуре:	Post Launch Change] [Final Version			Date:	20.0	8.24	
			PRODUCT INFORMAT	TION						SPECIAL HAND	DLING AND STOR	AGE REQUIF	REMENTS*			
Company Name:	Eugia US LLC					Applica	tion:	ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA; PMA/510	0(k): 203082									Controlled Room -		and 25 C (68	3° – 77° F)		
Medical Device Class, if applicat																
DUNS:	968961354									Other Temperature Range F	Requirement					
Proprietary Name (If Applicable) a		lame: Lidocai	ne Hydrochloride Injection,	USP						(write in)						
Selling Unit NDC: UDI	55150-164-02		Unit of Use NDC: CVX Code:		55150-164-02	UPC: MVX Code:	35515016	64028	-	Notes						
						MVX Code:			-							
Description:	Lidocaine Hydroc	chloride Injection USP,	2% 40mg/2mL (20mg/mL)	[Single Dose Vi	als]					Is this product to be shipped				No		
Active Ingredient(s):		Lidocaine Hydrochlo	rido LICD						-	Is this product to be shipped	to customers on d	ry ice?		No		
Active ingredient(s):		Lidocaine Hydrochid	ilide USP						h Contact for	temperature excursion que	astions:					
URL for Additional Product Inforn	nation:	https://eugiaus.c	com/products/? sft alp	phabet=m						Name:	cottons.	Eugia US Cu	stomer Serv	ice		
Address:	279 Princeton-Hig		,			Address 2:				Number:		888-238-788				
City:	East Windsor				State:	NJ	Zip: 0	8520		Group E-mail:		Customers	ervice@Eu	igiaUS.com		
Key Contact:					Email:											
Phone Number:	888-238-7880				Fax:	732-355-9449				lations for product in any				No		
Product Therapeutic Classification	n:	ANESTHETIC								Special returns requirement	s for this product?			No		
	ADDITI	IONAL PRODUCT INF	ODMATION			PRODUCT	DESCRIPT	ION INFORMATION	1							
	ADDITI	IONAL PRODUCT INF				PRODUCTI	DESCRIPT	ION INFORMATION	11	ct (unit of sale) upright?				No		
The product is?			Is the Product	Direct-Ship (Only		4.0	0 117.1		Protect product (unit of sa	ale) from light?			No		
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit of Use		Size:	10	x 2 mL Vials	e. Shelf life:	Initial shelf life at launch (if different).			36	Months Months	
a product kit?		No	Orphan Drug Status				40	mg/2 mL(20 mg/mL)		initial shell life at launch (ir different):				Wonths	
if yes, list NDCs of		IVO	FDA Approval Status			Strength:	10	mg/2 mc(20 mg/mc)			ORDER INFORM	ATION				
component parts						Danama Fam	Lic	quid								
reverse numbered?		No				Dosage For	m:			Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							Bottle		1 Box of 10 \				
latex-free?		Yes				Product Sha	pe: Via	al Pack		x Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
preservative-free?		Yes								Ampule						
correctional institution block? opioid?		No No				Product Col	or:		-	Glass Tube		Minimum o	der quantity	/	Yes	
Cannabinoid?		No	Country of Origin	India						Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	nit dose for		Country or origin			Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of whi	ich package	type?	
hospital scanning?			Is this product covered u	nder the						Vial Powder Sql			Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (7	ΓAA)?	No					Vial Power Multi			Inner/Carton	/Pack		
										Other: Write In		1	Case			
		l e	FOR GENERIC DRUG PRO	DDUCTS												
							*16 A th	i1 Oi1b		DU	ARMACY ORDER	/ DILL LINET				
				_	Aut	thorized Generic		ized Generic, other elds are not applicable			ARMACT ORDER					
I. Orange Book Rating:	AP	Videosino@ /lideosin	ie HCI) Injection – Methyl Pa	araban Fras /M	DE) 20/		SCOTION	sids are not applicable	Rec. sell unit to		1	Rx billing u		acy:		
II. Generic Equivalent to What Bra	ina ?:	Aylocalrie® (ildocalr	ie nci) injection – Methyl Pa	araben Free (ivi	PF) 2%				(Write-in, e.g. 1	10 Vials		X	Each Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION				HCPCS J-Code				Milliliter			
			•	,												
Does supplier meet DSCSA defini	tion of manufactu	urer?	Yes		GLN:					ITEM	AND PACKING IN	FORMATION				
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:					Weight Lbs.	Dimensio	ons (US msm	ıts.)	Volume	Saleable #	
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No	_		iginal product			Item/Each:	0.21	3.54	1.38	1.77	8.647	10	
Is product sold by manufacturer's Has FDA granted waiver/exception			No		-	rect from mfr? ce manufacturer f	or ropes!	and product	Box/Carton/Bu							
If yes, attach documentation from		oroduct?			Provide source	ce manuracturer i	ог гераска	igea product	Inner Pack:	inale/						
ii yes, attaon accumentation not	III DA.								Case:	00.007				4045.00	4000	
		GTIN	AND HIBCC PRODUCT IN	IFORMATION						26.637	15.55	12	8.66	1615.96	1200	
									Pallet:	1471.459	48	40	56.97	109382.4	64800	
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	ι	Init of Use GTIN-14		1471.409	40	40	30.37	109302.4	04000	
II		Quantity			0.55	F4F0404000	-									
x Item/Each Box/Carton/Bundle/Inner Pack		10			0038	55150164028				COST INFORMATION			NHOLESAL	ER USE ONL	v	
Box/Carton/Bundle/Inner Pack Case		1200			6034	55150164020				COST INFORMATION		\ \	MOLESALI	ER USE UNL		
x Case Pallet		64800				55150164024			Regular Cost			Vendor #:				
									Invoice Cost (\	NAC) (\$)	\$33.33	Whsl. Code	#:			
												Fineline Co	de:			
									As of date:	9/10/2024						
									[]							
H			Attach copy of SAFETY DA	TA CLIEFT (CC	C) as no - t	diamar DAOKAGE	INICEDT :	ADEL AND DUOTO OF	DDODUCT DACKS	CINC and DADOODE		<u> </u>				
*Place provide any additional inf	ormation on need		Auach copy of SAFETY DA	IA SHEET (SD	or non hazar			ABEL AND PHOTO OF	PRODUCT PACKA	GING AND BARCODE.		Г) Venkata Su	render Reddy	,	



Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, c. Contact Hazard? No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned NCPDP#: Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry:

Registry Program Contact Name ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: Yes **CLASS OF TRADE RESTRICTION:** 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 Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments:



Version 2024

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time:							
b. Autofax Fax Number:								
c. Fax Fax Number:	Shipping lead time of PO: Hours Days							
d. Phone No.:								
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:							
Minimum Order Quantity:	Ships for second day receipt:							
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:							
Contracted 3PL company / contact #: Name: Phone:								
	Overwight and Brigaity Overwight DO Breezesing							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order:	PO Receipt cut off time:							
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday							
Comments:	Tuesday							
	Wednesday							
	Thursday							
	Friday Friday							
	Priority Overnight receipt available:							
Class of Trade Restriction:	PO Receipt Cut off time:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:							
Restricted to retail pharmacy only:	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only:	Phone:							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	EDI:							
	Overnight Fees apply:							
	Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date:	Contact # if product is received damaged:							
Physician Name:	Is product returnable for credit:							
Physician/Clinic Phone #	URL/Link to returns policy:							
Physician State License #								
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?							
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?							
	Is product order for restocking purposes?							
	To product for recomming parposes.							



Version 2024						Introduction	Type: P	Post Launch Change		Final Version			Date:	20.0	8.24	
			PRODUCT INFORMAT	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*			
Company Name:	Eugia US LLC					Applica	tion:	ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	NDA/BLA; PMA/51	0(k): 207182	2							mperature Range	Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applical																
DUNS:	968961354								Ot	her Temperature Range	Requirement					
Proprietary Name (If Applicable) a		lame: Lidocai	ne Hydrochloride Injection,	USP						(write in)						
Selling Unit NDC: UDI	55150-254-10		Unit of Use NDC: CVX Code:		55150-254-10	UPC: MVX Code:	355150254	101	No	otes						
-						WVX Code:										
Description:	Lidocaine HCI Inj	jection USP (MDV) 2%								this product to be shipped				No		
Active Ingredient(s):		Lidocoino Hudrooblo	oride USP 2% 200mg/10mL	/10ma/ml \ Mi	ultiple Dose Viele	•			Is	this product to be shipped	to customers on o	dry ice?		No		
Active ingredient(s):		Lidocairie Hydrochid	onde USP 2% 200mg/TomL	(TOTTIG/TITE) IVII	Jupie Dose viais	8			h Contact for ter	nperature excursion qu	estions:					
URL for Additional Product Inforr	mation:	https://eugiaus.c	com/products/? sft alp	ohabet=m						me:	conons.	Eugia US C	ustomer Serv	ice		
Address:	279 Princeton-Hi					Address 2:			No	ımber:		888-238-788				
City:	East Windsor				State:	NJ	Zip: 085	520	Gi	oup E-mail:		<u>Customer</u> :	Service@Eu	igiaUS.com		
Key Contact:					Email:											
Phone Number:	888-238-7880				Fax:	732-355-9449				tions for product in any				No		
Product Therapeutic Classificatio	on:	ANESTHETIC							Sp	ecial returns requiremen	ts for this product?			No		
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									.							
	ADDITI	IONAL PRODUCT INF				PRODUCT	DESCRIPTIO	IN INFORMATION	1	(unit of sale) upright?				Yes		
The product is?			Is the Product	Direct-Ship	Only					otect product (unit of s	ale) from light?			No		
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit of Use		Size:	25 x	10 mL Vials	e. Shelf life:	itial shelf life at launch (if different):			36	Months Months	
a product kit?		No	Orphan Drug Status				200	mg/10 mL(20	in in	itiai sneii ille at launch (ir different):				Wonths	
if yes, list NDCs of		140	FDA Approval Status			Strength:	mg/r				ORDER INFORM	MATION				
component parts						Dosage For	Liqui	id								
reverse numbered?		No				Dosage For	m:		Uı	nit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							Bottle		1 Box of 25				
latex-free?		Yes				Product Sha	ape: Vial	Pack		x Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)		
preservative-free?		No								Ampule Glass						
correctional institution block? opioid?		No No				Product Col	or:			Tube		winimum o	rder quantity	/	Yes	
Cannabinoid?		No	Country of Origin	India						Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for	140	Country of Origin	maia		Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of wh	ich package	type?	
hospital scanning?	ariit addo roi		Is this product covered u	nder the						Vial Powder Sql		,	Each	pg-	.,,,,	
If Unit Dose, indicate NDC here:			Trade Agreements Act (No					Vial Power Multi			Inner/Carton	/Pack		
										Other: Write In		1	Case			
			FOR GENERIC DRUG PR	DDUCTS												
										BU	ADMAQY ORDER	/ DULL LINUT				
				_	Au	thorized Generic		ed Generic, other ds are not applicable			ARMACY ORDER					
I. Orange Book Rating:	AP	V. 1i @ //i-1i	- 1101) Indiantian 00/	f t		0.4	Section neit	as are not applicable	Rec. sell unit to		1		nit to pharm	acy:		
II. Generic Equivalent to What Bra	and?:	Xylocaine® (lidocain	ne HCl) Injection – 2% man	utactured by F	resenius Kabi U	SA				25 Vials		X	Each Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFO	RMATION				(Write-in, e.g. 1 V	iai)			Milliliter			
			(,					1101 00 0 00001		1		I I I I I I I I I I I I I I I I I I I			
Does supplier meet DSCSA defini	ition of manufacti	urer?	Yes		GLN:					ITEM	AND PACKING IN	NFORMATIO	١			
Is product exempt from DSCSA?	•		No													
If yes, select exemption:					GCP:					Weight Lbs.	Dimensi	ons (US msn	nts.)	Volume	Saleable #	
Other exemption - Write in:										weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No			riginal product			Item/Each:	1.6	5.55	5.55	2.75	84.707	25	
Is product sold by manufacturer's			No		•	irect from mfr?									-	
Has FDA granted waiver/exceptio		product?			Provide sour	ce manufacturer f	or repackage	ed product	Box/Carton/Bund	ile/						
If yes, attach documentation fro	om FDA.								Case:							
		GTIN	AND HIBCC PRODUCT IN	FORMATION					l Gasc.	13.91	11.81	11.81	6.29	877.30	200	
									Pallet:	1200 414	40	40	EE 20	106348.8	10200	
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Un	it of Use GTIN-14		1368.414	48	40	55.39	106348.8	19200	
		Quantity					_									
x Item/Each		25			003	55150254101				COST INFORMATION			NUOI EO	ED LIGE ON	٧.	
Box/Carton/Bundle/Inner Pack X Case		200			500	55150254106				COST INFORMATION			WHOLESAL	ER USE ONL	11:	
A Case		19200				55150254106			Regular Cost			Vendor #:				
x Pallet									Invoice Cost (WA	AC) (\$)	\$91 44	Whsl. Code	#-			
x Pallet																
x Pallet									invoice cost (W)		******	Fineline Co				
X Pallet									As of date:	9/10/2024	•					
x Pallet											7					
X Pallet			Attach copy of SAFETY DA	TA 01/5					As of date:	9/10/2024	•					



Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, c. Contact Hazard? No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned NCPDP#: Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry:

Registry Program Contact Name ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: Yes **CLASS OF TRADE RESTRICTION:** 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 Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments:



Version 2024

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time:							
b. Autofax Fax Number:								
c. Fax Fax Number:	Shipping lead time of PO: Hours Days							
d. Phone No.:								
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:							
Minimum Order Quantity:	Ships for second day receipt:							
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:							
Contracted 3PL company / contact #: Name: Phone:								
	Overwight and Brigaity Overwight DO Breezesing							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order:	PO Receipt cut off time:							
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday							
Comments:	Tuesday							
	Wednesday							
	Thursday							
	Friday Friday							
	Priority Overnight receipt available:							
Class of Trade Restriction:	PO Receipt Cut off time:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:							
Restricted to retail pharmacy only:	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only:	Phone:							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	EDI:							
	Overnight Fees apply:							
	Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date:	Contact # if product is received damaged:							
Physician Name:	Is product returnable for credit:							
Physician/Clinic Phone #	URL/Link to returns policy:							
Physician State License #								
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?							
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?							
	Is product order for restocking purposes?							
	To product for recomming parposes.							