

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021						Introduction T	Гуре:	New Item		Final Version			Date:	6/15/	5/2022
			PRODUCT INFORMAT	TION						SPECIAL H	ANDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Eugia US LLC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN		0(k)(med device	:e):	20	18703				u. remperata	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical			,-						•						
DUNS:	968961354									Other Temperature Rang	e Requirement	Store at 20°	to 25°C (68°	to 77°F) [see	USP
Proprietary Name (If Applicable) a	and Established Name:	Thiam	ine HCI							(write in)	•	Controlled F	Room Tempe	rature].	
Selling Unit NDC:	55150-273-25		Unit of Use NDC:		55150-273-01	UPC:	355150	0273256		Notes					
UDI			CVX Code:			MVX Code:									
Description:	Thiamine HCI Injection,	, USP 200 mg p	er 2 mL(100 mg / mL) [MDV]	25 vials						Is this product to be ship	ed to customers on i	ce?		No	1
										Is this product to be ship	ed to customers on o	dry ice?		No	
Active Ingredient(s):	Thia	amine HCI													
									b. Contact for	temperature excursion	questions:				
URL for Additional Product Inform Address:	279 Princeton-Hightsto	Daad			1	Address 2:				Name: Number:		Kevin Cagn 732.839.940			
City:	East Windsor	WII KOAU			State:	NJ	Zin:	08520		Group E-mail:				om	
Key Contact:	Lust Willuson				Email:	140	Lip.	00020	Group E-mail.			kcagnetti@EugiaUS.com			
Phone Number:	888-238-7880				Fax:	732-355-9449	32-355-9449			c. Special regulations for product in any states?			No		
Product Therapeutic Classificatio	on: Vita	ımin B1								Special returns requirem	ents for this product?			No	1
															1
	ADDITIONAL	L PRODUCT IN	FORMATION			PRODUCT	DESCRI	IPTION INFORMATION	d. Store prod	uct (unit of sale) upright				No	
The product is?			Is the Product	Direct-Ship (Only					Protect product (unit of	sale) from light?				i .
a legend device?	No		Is the Product	Neither		Size:		Multiple Dose Vials	e. Shelf life:	, ,	, •			18	Months
if yes, enter class #			Orphan Drug Status			Size.				Initial shelf life at launc	n (if different):				Months
a product kit?	No					Strength:		200 mg per 2 mL							
if yes, list NDCs of			FDA Approval Status					1.5			ORDER INFORM	IATION			
component parts reverse numbered?	No					Dosage Forn	m:	Liquid		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	No		Allergens Present				l.			Bottle		1 box of 25		unit.	
latex-free?	Yes		/ morgono i rocom			Beer dead Observed		Vial Pack		x Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?	Yes					Product Sha	ipe:			Ampule		, , , ,		,	
correctional institution block?	No					Product Cole	or.			Glass		Minimum o	rder quantity	/?	Yes
opioid?	No					1 Todact Con				Tube					
Cannabinoid?	No		Country of Origin	India		Product Imp	rint:			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		Is this product covered u				Į.			Vial Liquid Mul		If Yes, how		ich package t	type?
hospital scanning? If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No					Vial Powder So			Each Inner/Cartor	n/Pack	
II Offit Dose, indicate NDC fiere.			Trade Agreements Act (1	701):	140					Other: Write In		1	Case	I/I ack	
			FOR GENERIC DRUG PR	ODUCTS											
					Au	thorized Generic	*If Auth	horized Generic, other			PHARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating: AP					section fields are not applicable Rec. set			to customer?	Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Thiamine HCl Injection							1 vial				x Each				
									(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFO	RMATION								Milliliter		
Dana assemblias mant DSCSA defini	itian of manufactures?		Yes	_	CI N.					IT	EM AND PACKING I	NEORMATIO	M		
Does supplier meet DSCSA defini Is product exempt from DSCSA?			No	-	GLN:						-M-AND PACKING II	AI ONWIATIO			
			110		000						Dimensi	ons (US msr	nto \	M-1	0-11-1-#
If yes, select exemption: Other exemption - Write in:					GCP:					Weight Lbs	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes, was or	iginal product			Item/Each:					<u> </u>	
Is product sold by manufacturer's	s exclusive distributor?		No			rect from mfr?			non y zaom	0.54378	3.54	3.54	1.97	24.687252	25
Has FDA granted waiver/exceptio			No		Provide source	ce manufacturer fo	or repact	kaged product	Box/Carton/B	undle/					
If yes, attach documentation from	m FDA.								Inner Pack:						
									Case:	29.84	15.944	12.4	11.22	2218.2568	48
		GII	N AND HIBCC PRODUCT I	NFORMATION					Pallet:						
Saleable Unit of Measure	Salaah	ole Quantity	HIBCC		GTII	N-14		Unit of Use GTIN-14	Pallet:	1107.30	48	40	50.12	96230.40	1728
X Item/Each	Saleat	25	ПВСС			55150273256		Utilit of Use GTIN-14	L						
Box/Carton/Bundle/Inner Pack										COST INFORMATIO	N		WHOLESAL	ER USE ONL	_Y:
Case		48			503	55150273251									
Pallet		1728			703	55150273255			Regular			Vendor #:			
									Invoice Cost	(WAC) (\$)	\$164.35	Whsl. Code			
					_				An of deter	8/18/2022		Fineline Co	de:		
							_		As of date:	0/10/2022		1			
			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza	rd letter. PACKAGE	INSER	T, LABEL AND PHOTO OF P	RODUCT PACK	AGING and BARCODE					



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIA	. 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? N	SDS Hazard Classification Organic Corrosive					
Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning?	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? N	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	Is the product a NIOSH hazardous drug? If yes, indicate which:					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard?						
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: DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:					
Is the Product	Continents					
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged:					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: No.						
Restricted to hospital, clinics, and physician offices only: No. Restricted from US territories? (explain in comments)	product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
MISCELL	ANEOUS NOTES and/or Image of Product Barcode:					



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

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 only	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:	N	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #:	Name:	
	Phone:	
Expedited Freight Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each orde	r:	Overnight receipt available:
Drop Ship service fee billed with each orde	r:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Cla	ss of Trade Restriction:	PO Receipt Cut off time:
	narmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	larmacy, nospitals, clinics and physician onices	PO Receipt Cut off time:
Restricted to retail pharmacy only. Restricted to hospital, clinics, and physician	o offices only:	Phone:
Restricted from US territories? (explain in c		Order receipt method: Fax: Fax #:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Inf	ormation Required to Process PO:	Return Instructions
Patient Procedure Date:		Contact # if product is received damaged: Is product returnable for credit:
Physician Name: Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		OND Link to returns policy.
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
	/liscellaneous Notes:	,
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?