

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

Version 2024							Introduction 7	Туре:	New Item		x Final Ve	rsion			Date:	6/27/	/2025
				PRODUCT INFORMA	TION						SPEC	IAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANI	DA/BLA; PMA/510)(k):	218471				NDA 505(b) Type	NOT AF	PLICABLE		Temperature Rang		Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:																
DUNS:	11-856-3719										Other Temperature	e Range R	equirement	Do Not Free	ze.		
Proprietary Name (If Applicable) a	nd Established Na 31722-363-32	ame:	Thiamine	Hydrochloride Injection, Unit of Use NDC:	JSP 200 mg/2 n	nL (100 mg/mL 31722-363-32					(write in)						
Selling Unit NDC: UDI	31722-363-32			CVX Code:		31722-363-32	UPC: MVX Code:	331722363327		-	Notes						
-							III VX Gode.			I I							1
Description:	I niamine Hydrocr	nioriae injectio	on, USP 20	00 mg/2 mL (100 mg/mL) !	viuitipie-Dose v	ais					Is this product to b					No No	
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No No									l								
										b. Contact fo	r temperature excu	ırsion que	stions:				
URL for Additional Product Inform Address:		www.cambe	rpharma.co	<u>om</u>			Address 2:			+	Name: Number:			Soma Raju 732-529-042	23		
City:	Piscataway	Centennial Ave, Suite 1			NJ Zip: 08854			Group E-mail: somaraju@heterousa.com									
Key Contact:	Customer Service	9				Email:	-	@camberpharma.	com						=		
Phone Number:	1-866-827-3647					Fax:	732-562-8788			c. Special regulations for product in any states? *Yes							
Product Therapeutic Classification	n:	Vitamin B ₁	dificiency s	upplement							Special returns red	quirements	for this product?			No	
	ADDITI	ONAL PROD					PRODUCT	DESCRIPTION IN	FORMATION	d. Store prod	luct (unit of sale) u					No	
The product is?				Is the Product	Direct-Ship C	nly					Protect product (unit of sal	e) from light?			No	
a legend device? if yes, enter class #		No		Is the Product Orphan Drug Status	Unit of Use		Size:	25 x 2 ml	_ multiple-dose	e. Shelf life:	Initial shelf life at	laumah (H	different).			18	Months
a product kit?		No		Orphan Drug Status					mL per multiple-		initial shell life at	launch (II	amerent):				Months
if yes, list NDCs of		140		FDA Approval Status			Strength:	dose vial					ORDER INFORM	IATION			
component parts							Dosage Fori	Sterile, c	ear solution								
reverse numbered?		No					Dosage i on				Unit of Sale				NDC selling		
co-licensed? latex-free?		No	-	Allergens Present Sodium Hydroxide manufacturer in	forms that latex contain	ning material		N/A			x Box/Carl				25 x 2 mL Mu .g. 1 Box of 10		ials
preservative-free?		Yes No	-	(rubber) might be used in technical	components like gask	ets or inliners	Product Sha	ape:			x Box/Carl	tori		(vvrite-in, e.	.g. i box oi it	J viais)	
correctional institution block?		No		for processing	and nandling.			Colorless			x Glass			Minimum o	rder quantity	?	Yes
opioid?		No					Product Col	lor:			Tube						
Cannabinoid?		No		Country of Origin	India		Product Imp	orint: N/A			Vial Liqu						
If Unit Dose, is item bar coded to u	nit dose for										x Vial Liqu				many of whi	ch package t	type?
hospital scanning? If Unit Dose, indicate NDC here:				Is this product covered u Trade Agreements Act (1		No					Vial Pow Vial Pow			1	Each Inner/Carton	/Pack	
II Offit bose, indicate NDC fiere.				riade rigicements riot (1	701):	INO					Other: W				Case	/I dok	
			F	OR GENERIC DRUG PR	ODUCTS					_							
					_	Au	thorized Generic	*If Authorized G				PHA	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP	leer or or or			1 (100			section fields an	e not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:					acy:		
II. Generic Equivalent to What Brand?: Thiamine Hydrochloride Injection, USP 200 mg/2 mL (100 mg/mL) Multiple-Dose				se Vials of Freseniu	us Kabi USA, LLC		(Write-in, e.g. 1 Vial) Each										
		DRUG	SUPPLY (CHAIN SECURITY ACT (DSCSA) INFOR	MATION				HCPCS J-Co					Milliliter		
				,	,						J3411				-		
Does supplier meet DSCSA definit	tion of manufactur	rer?		Yes		GLN:	0331722498975					ITEM	AND PACKING IN	IFORMATIO	N		
Is product exempt from DSCSA?				No													
If yes, select exemption:						GCP:					Weigl	ht Lbs.		ons (US msr		Volume	Saleable #
Other exemption - Write in: Is product repackaged?				No		If was	iginal product pur	rehand		Item/Each:	_		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	evelusive distribu	ıtor?		Yes	-	direct from m		rcnased		item/Each:	0	.48	3.4	3.4	2.19	25.32	1
Has FDA granted waiver/exception				No	+		 ce manufacturer fo	or repackaged pr	oduct	Box/Carton/E	Bundle/						
If yes, attach documentation from	n FDA.									Inner Pack:							
			OTIN A	AND HIBCC PRODUCT II	IFORMATION.					Case:	9	.65	11	11	5.5	665.50	18
			GIIN A	AND HIBCC PRODUCT IF	NFURMATION					Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable		HIBCC		GTI	N-14	Unit of	Jse GTIN-14	l l allet.							
		Quantity															
x Item/Each	N	1				003	31722363327	003317	22363327		000=111=0=						
Box/Carton/Bundle/Inner Pack	N	10	-			202	21722262221	_			COST INFORI	WATION			WHOLESALE	ER USE ONL	.Y:
X Case Pallet	N	18	-			203	31722363321	_		Regular Cost	•	ı		Vendor #:			
1 circs										Invoice Cost			\$150.00	Whsl. Code	#:		
													Ţ.23.00	Fineline Co			
										As of date:	6/25/202	25		ļ			
H				ttach copy of SAFETY DA	TA QUEET (OD	C) or non h-=-	rd lottor BACKACE	E INCEDT I APE	AND BHOTO OF B	DECULICT BACK	ACINC and BARCO	DE		<u> </u>			
*Please provide any additional info	ormation on page	2	A	uacii copy oi SAFETY DA	IIM SHEET (SL	oj or non naza		E INSERT, LABEL r Designated Dro		-NODUCI PACK	Signature	DE.					



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

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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? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	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	Is the product a NIOSH hazardous drug? If yes, indicate which:						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
	ET ATTRIZENDOUS WASIE COUC.						
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	REMS OF REGISTRE RESTRICTIONS						
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 e. Inhalation Hazard?	Website URL:						
	Med Guide Required No						
Is the product restricted for air shipment? If so, indicate restriction: No Passenger	Med Guide Required Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)	Wholesale distributor support: Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments						
	Onninenta						
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No	NETOWN MOTION						
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: No	product in certain states? Yes						
Restricted from US territories? (explain in comments) No	If so, which states? Other requirements? Comments?						
Comments:	Sodium hydroxide: Listed on the United States TSCA (Toxic Substances Control Act) inventory, Massachusetts - Right To Know List, Minnesota - Hazardous Substance List, New Jersey - Right to Know Hazardous Substance List, Pennsylvania - RTK (Right to Know) List						
MISCELLANE(DUS NOTES and/or Image of Product Barcode:						
IMIOCELEARIES							



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

Purchase order ally receipt cut off time by supplier a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing					
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier					
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No. Expedited freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:					
d. Phone only e. Suppler Web Site only Site Address: Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Dry Receipt day for the fire: Dry Receipt day receipt								
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone: Expedited Freight Carlanges or Other Designated Drop Ship Fees: Expedited Freight Carlanges or Other Designated Drop Ship Fees: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi			Shipping lead time of PO: Hours Days					
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