



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

Version 2024 Introduction Type:  New Item  Final Version Date: 11/19/2025

**PRODUCT INFORMATION**

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA; PMA/510(k): 218471 NDA 505(b) Type: NOT APPLICABLE  
 Medical Device Class, if applicable:  
 DUNS: 11-856-3719  
 Proprietary Name (If Applicable) and Established Name: Thiamine Hydrochloride Injection, USP 200 mg/2 mL (100 mg/mL) Multiple-Dose Vials  
 Selling Unit NDC: 31722-363-32 Unit of Use NDC: 31722-363-32 UPC: 331722363327  
 UDI  
 CVX Code: MVX Code:  
 Description: Thiamine Hydrochloride Injection, USP 200 mg/2 mL (100 mg/mL) Multiple-Dose Vials  
 Active Ingredient(s): Thiamine hydrochloride, USP  
 URL for Additional Product Information: [www.camberpharma.com](http://www.camberpharma.com)  
 Address: 800 Centennial Ave, Suite 1 State: NJ Address 2:  
 City: Piscataway Zip: 08854  
 Key Contact: Customer Service Email: [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
 Phone Number: 1-866-827-3647 Fax: 732-562-8788  
 Product Therapeutic Classification: Vitamin B, deficiency supplement

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range:  Controlled Room – between 20 and 25 C (68° – 77° F)  
 Other Temperature Range Requirement:  Do Not Freeze.  
 (write in)  
 Notes:  
 Is this product to be shipped to customers on ice?  No  
 Is this product to be shipped to customers on dry ice?  No  
 b. Contact for temperature excursion questions:  
 Name: Soma Raju  
 Number: 732-529-0423  
 Group E-mail: [somaraju@heterousa.com](mailto:somaraju@heterousa.com)  
 c. Special regulations for product in any states?  
 Special returns requirements for this product?  No  
 d. Store product (unit of sale) upright?  No  
 Protect product (unit of sale) from light?  No  
 e. Shelf life:  
 Initial shelf life at launch (if different): 18 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? if yes, enter class #	<input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status	<input type="checkbox"/> Direct-Ship Only <input type="checkbox"/> Unit of Use
if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	FDA Approval Status	Size: 25 x 2 mL multiple-dose vials
co-licensed?	<input type="checkbox"/> No	Allergens Present	Strength: 200 mg/2 mL per multiple-dose vial
latex-free?	<input type="checkbox"/> No*	* Sodium Hydroxide manufacturer informs that latex containing material (rubber) might be used in technical components like gaskets or liners for processing and handling.	Dosage Form: Sterile, clear solution
preservative-free?	<input type="checkbox"/> No	Country of Origin	Product Shape: N/A
correctional institution block?	<input type="checkbox"/> No	India	Product Color: Colorless
opioid?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	Product Imprint: N/A
Cannabinoid?	<input type="checkbox"/> No	<input type="checkbox"/> No	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:	<input type="checkbox"/>		

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Carton of 25 x 2 mL Multiple-Dose Vials
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input checked="" type="checkbox"/> Glass Tube	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Vial Liquid Sgl	
<input checked="" type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	1 Each
<input type="checkbox"/> Vial Powder Multi	Inner/Carton/Pack
<input type="checkbox"/> Other: Write In	Case

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating: AP  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?: Thiamine Hydrochloride Injection, USP 200 mg/2 mL (100 mg/mL) Multiple-Dose Vials of Fresenius Kabi USA, LLC

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  Each  
 Gram  
 Milliliter  
 (Write-in, e.g. 1 Vial)  
 HCPCS J-Code: J3411

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 Is product exempt from DSCSA?  Yes  No  
 If yes, select exemption:  
 Other exemption - Write in:  
 Is product repackaged?  No  
 Is product sold by manufacturer's exclusive distributor?  Yes  
 Has FDA granted waiver/exception/exemption for product?  No  
 If yes, attach documentation from FDA.  
 GLN: 0331722498975  
 GCP:  
 If yes, was original product purchased direct from mfr?   
 Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.48	3.4	3.4	2.19	25.32	1
Case:	9.65	11	11	5.5	665.50	18
Pallet:						

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722363327	00331722363327
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack					
<input checked="" type="checkbox"/> Case	N	18		20331722363321	
<input type="checkbox"/> Pallet					

**COST INFORMATION**

Regular Cost  
 Invoice Cost (WAC) (\$) \$150.00  
 As of date: 6/25/2025

**WHOLESALE USE ONLY:**  
 Vendor #:  
 Whsl. Code #:  
 Fineline Code:

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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?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
 Is the product a CA Prop 65 carcinogen?  No  
 Is the product a CA Prop 65 reproductive toxicant?  No  
 Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT?  
 (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA?  
 (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  No
- Cargo  No
- Passenger & Cargo  No

Is this a reportable quantity?  No

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- No (if yes, identify method below)
- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101);  
 SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes      Controlled Substance Code
- Controlled by State(s)?  No  Yes      Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes      If yes, indicate which:
- Schedule No.       Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No

If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:       Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes

If Yes, is it managed with a pharmacy registry?  No  Yes

Website URL:

Med Guide Required  No  Yes

Limited Distribution Requirement  No  Yes

Comments / Details: (For example, iPledge program?)

**REMS:**  No  Yes

REMS Program Manager Name:       Phone:

Supplier Manages REMS registry exclusively:  No  Yes

Wholesale distributor support:  No  Yes

Provider Name:       DEA #:

Site Enrollment Number assigned by Supplier:       NCPDP#:

NPI #:

Comments

**Registry:**  No  Yes

Registry Program Contact Name:       Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647

Is product returnable for credit:  Yes  No

URL/Link to returns policy:  contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:



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

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