



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 10/17/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/>		Application: <input type="text" value="ANDA"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="204574"/>				Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in) <input type="text"/>			
DUNS: <input type="text" value="11-856-3719"/>				Notes <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Tetrabenazine Tablets 12.5 mg"/>		Selling Unit NDC: <input type="text" value="31722-821-11"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
UDI <input type="text"/>		Unit of Use NDC: <input type="text" value="31722-821-11"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
CVX Code: <input type="text"/>		UPC: <input type="text" value="331722821117"/>					
MVX Code: <input type="text"/>							
Description: <input type="text" value="Tetrabenazine Tablets 12.5 mg"/>				<b>b. Contact for temperature excursion questions:</b>			
Active Ingredient(s): <input type="text" value="Tetrabenazine"/>				Name: <input type="text" value="Soma Raju"/>			
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				Number: <input type="text" value="732-529-0423"/>			
Address: <input type="text" value="800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>					
Key Contact: <input type="text" value="Customer Service"/>		Zip: <input type="text" value="08854"/>					
Phone Number: <input type="text" value="1-866-827-3647"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>					
Product Therapeutic Classification: <input type="text" value="Vesicular monoamine transporter 2 (VMAT) inhibitor"/>		Fax: <input type="text" value="732-562-8788"/>					
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION				
The product is? a legend device? if yes, enter class # a product kit? if yes, list NDCs of component parts reverse numbered? co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="text" value="No"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Is the Product... Direct-Ship Only Unit of Use Orphan Drug Status FDA Approval Status Allergens Present Country of Origin	<input type="text" value="Direct-Ship Only"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text" value="India"/>	Size: Strength: Dosage Form: Product Shape: Product Color: Product Imprint:	<input type="text" value="112 ct"/> <input type="text" value="12.5 mg"/> <input type="text" value="Non-scored tablet"/> <input type="text" value="Round, flat, bevel edged"/> <input type="text" value="White to off white"/> <input type="text" value="Debossed with 'H' on one side and 'T5' on the other side"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:	<input type="text"/> <input type="text"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>				
ORDER INFORMATION							
Unit of Sale			What is the NDC selling unit?				
<input checked="" type="checkbox"/> Bottle			<input type="text" value="1 Bottle of 112 Tablets"/>				
<input type="checkbox"/> Box/Carton			(Write-in, e.g. 1 Box of 10 Vials)				
<input type="checkbox"/> Ampule							
<input type="checkbox"/> Glass			Minimum order quantity? <input type="text" value="Yes"/>				
<input type="checkbox"/> Tube							
<input type="checkbox"/> Vial Liquid Sgl			If Yes, how many of which package type?				
<input type="checkbox"/> Vial Liquid Multi			<input type="text" value="24"/> Each				
<input type="checkbox"/> Vial Powder Sgl			<input type="text"/> Inner/ Carton/ Pack				
<input type="checkbox"/> Vial Powder Multi			<input type="text"/> Case				
<input type="checkbox"/> Other: Write In							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="text"/>			Rx billing unit to pharmacy:				
(Write-in, e.g. 1 Vial)			<input type="text"/> Each				
			<input type="text"/> Gram				
			<input type="text"/> Milliliter				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="0331722498975"/>					
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP: <input type="text"/>					
If yes, select exemption: Other exemption - Write in: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>			
Is product repackaged? <input type="text" value="No"/>							
Is product sold by manufacturer's exclusive distributor? <input type="text" value="Yes"/>							
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>							
If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14			
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722821117"/>	<input type="text" value="00331722821117"/>			
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack							
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>		<input type="text" value="10331722821114"/>				
<input type="checkbox"/> Pallet							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost		Invoice Cost (WAC) (\$)		Vendor #:		<input type="text"/>	
		<input type="text" value="\$150.00"/>		Whsl. Code #:		<input type="text"/>	
As of date: <input type="text" value="3/1/2024"/>				Fineline Code:		<input type="text"/>	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  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)  No

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)  No

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:  No

- Passenger
- Cargo
- Passenger & Cargo

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

Does the product have an Aerosol class? If yes, identify  No

NFPA Storage Level:

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

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required  No

Limited Distribution Requirement

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

REMS:  No

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned by Supplier:

NCPDP#:

NPI #:

Comments

Registry:  No

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

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)

Version 2021

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 #: Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <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: 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"/>