



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

Version 2024 Introduction Type: Final Version Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*											
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA Application Number for NDA/ANDA/BLA; PMA/510(k): 217068 NDA 505(b) Type: NOT APPLICABLE Medical Device Class, if applicable: _____ DUNS: 11-856-3719 Proprietary Name (If Applicable) and Established Name: Lisdexamfetamine Dimesylate Chewable Tablets 10 mg Selling Unit NDC: 31722-321-01 Unit of Use NDC: _____ UPC: 331722321013 UDI: _____ CVX Code: _____ MXV Code: _____ Description: Lisdexamfetamine Dimesylate Chewable Tablets 10 mg Active Ingredient(s): Lisdexamfetamine dimesylate URL for Additional Product Information: www.camberpharma.com Address: 800 Centennial Ave, Suite 1 Address 2: _____ City: Piscataway State: NJ Zip: 08854 Key Contact: Customer Service Email: customerservice@camberpharma.com Phone Number: 1-866-827-3647 Fax: 732-562-8788 Product Therapeutic Classification: Central nervous system (CNS) stimulant				a. Temperature – Indicate the USP temperature range for this product. Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in): <input type="text" value="Excursions permitted to 15° to 30°C (59° to 86°F)"/> Notes: _____ Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/> b. Contact for temperature excursion questions: Name: <input type="text" value="Soma Raju"/> Number: <input type="text" value="732-529-0423"/> Group E-mail: <input type="text" value="somaraju@heterousa.com"/> c. Special regulations for product in any states? Special returns requirements for this product? <input type="text" value="*Yes"/>											
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION											
The product is? <input type="text" value="No"/> a legend device? if yes, enter class # _____ a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? _____ co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> preservative-free? <input type="text" value="No"/> correctional institution block? <input type="text" value="No"/> opioid? <input type="text" value="No"/> Cannabinoid? <input type="text" value="No"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? _____ If Unit Dose, indicate NDC here: _____		Is the Product... <input type="text" value="Direct-Ship Only"/> Is the Product... <input type="text" value="Neither"/> Orphan Drug Status: _____ FDA Approval Status: _____ Allergens Present: <input type="text" value="Corn, Alcohol, Animal, Sugar"/> Country of Origin: <input type="text" value="USA"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>		Size: <input type="text" value="100 ct"/> Strength: <input type="text" value="10 mg"/> Dosage Form: <input type="text" value="Chewable tablet"/> Product Shape: <input type="text" value="Round, biconvex"/> Product Color: <input type="text" value="White to off-white"/> Product Imprint: <input type="text" value="Debossed 'AT' on one side and '10' on the other side"/>		d. Store product (unit of sale) upright? <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): _____ Months									
ORDER INFORMATION															
Unit of Sale: <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In _____				What is the NDC selling unit? <input type="text" value="1 Bottle of 100 Chewable Tablets"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text" value="Yes"/>											
PHARMACY ORDER / BILL UNIT															
I. Orange Book Rating: <input type="text" value="AB"/> II. Generic Equivalent to What Brand?: <input type="text" value="Vyvanse Chewable"/>				Rec. sell unit to customer? _____ (Write-in, e.g. 1 Vial) HCPSC J-Code: _____				Rx billing unit to pharmacy: <input type="text" value="Each"/> <input type="text" value="Gram"/> <input type="text" value="Milliliter"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION															
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/> Is product exempt from DSCSA? <input type="text" value="No"/> If yes, select exemption: _____ Other exemption - Write in: _____ 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. _____				GLN: <input type="text" value="0860000397957"/> GCP: _____ If yes, was original product purchased direct from mfr? <input type="text" value="No"/> Provide source manufacturer for repackaged product: _____											
GTIN AND HIBCC PRODUCT INFORMATION															
Saleable Unit of Measure <input checked="" type="checkbox"/> Item/Each <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack <input type="checkbox"/> Case <input type="checkbox"/> Pallet		RFID tag(Y/N) <input type="text" value="N"/>		Saleable Quantity <input type="text" value="1"/> <input type="text" value="24"/>		HIBCC <input type="text" value="00331722321013"/> <input type="text" value="10331722321010"/>		GTIN-14 <input type="text" value="00331722321013"/> <input type="text" value="10331722321010"/>		Unit of Use GTIN-14 <input type="text" value=""/>					
ITEM AND PACKING INFORMATION				COST INFORMATION				WHOLESALE USE ONLY:							
		Weight Lbs.		Dimensions (US msmts.)		Volume		Saleable #							
		Depth		Width		Height		(Cube)		Pieces					
Item/Each:		0.07		1.56		1.56		2.94		7.16		1			
Box/Carton/Bundle/Inner Pack:															
Case:		1.62		10.8		7		3.2		241.92		24			
Pallet:															
Regular Cost Invoice Cost (WAC) (\$) <input type="text" value="\$1,107.95"/> As of date: <input type="text" value="9/18/2024"/>				Vendor #: _____ Whsl. Code #: _____ Fineline Code: _____											

*Please provide any additional information on page 2.

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? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? No
(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? No
(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: 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? Yes No Controlled Substance Code

Controlled by State(s)? Yes No Listed Chemical (List I or II) No

ARCOS Reportable? Yes No If yes, indicate which:

Schedule No. Is it a scheduled listed chemical product?: No

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

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

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:

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:

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:

Is product returnable for credit: Yes No

URL/Link to returns policy:

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

If so, which states? Other requirements? Comments?

DEA Form 222 or its electronic equivalent is required for all returns in all states.

MISCELLANEOUS NOTES and/or Image of Product Barcode:

*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.



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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"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	Purchase order daily receipt cut off time by supplier 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"/>	Overnight receipt available: <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 Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <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"/>