

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

Version 2024							Introduction T	Гуре:	New Item		x Final Version			Date:	11/8	/2024
				PRODUCT INFORMAT	TION						SPECIAL HAI	NDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.						Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA; PMA/510	0(k):	217442				NDA 505(b) Type:	:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:															
DUNS:	11-856-3719									,	Other Temperature Range	Requirement	Excursions	permitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a	and Established N 31722-355-01	ame:	Lisdexam	fetamine Dimesylate Cap Unit of Use NDC:	sules 60 mg						(write in)					
Selling Unit NDC: UDI	31722-355-01			CVX Code:			UPC: MVX Code:	331722	2355018	ł I	Notes					
0.77.0000								:						1		
Description:	Lisdexamtetamin	ne Dimesylate (Capsules 6	u mg							Is this product to be shipped is this product to be shipped.				No No	
Active Ingredient(s): Lisdexamfetamine dimesylate									is this product to be shippe	d to customers on t	ary 100 :		140			
									b. Contact for	temperature excursion qu	estions:					
URL for Additional Product Information: www.camberpharma.com				4.11				Name: Soma Raju Number: 732-529-0423								
Address:		nnial Ave, Suite 1			Address 2: State: NJ Zin: 08854				732-529-0423							
City: Key Contact:	Piscataway Customer Service	iloo				Email:	NJ Zip: 08854 customerservice@camberpharma.com		Group E-mail: somaraju@heterousa.com							
Phone Number:	1-866-827-3647	<u> </u>				Fax:	732-562-8788		c. Special regulations for product in any states?				*Yes			
Product Therapeutic Classificatio		Central nerv	ous systen	n (CNS) stimulant		702 002 0700				*Yes						
				()							Special returns requiremen					J
	ADDIT	IONAL PROD	UCT INFO	RMATION			PRODUCT I	DESCRI	IPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	1
The product is?				Is the Product	Direct-Ship C	Only					Protect product (unit of s	ale) from light?			No	1
a legend device?		No		Is the Product	Neither		Size:		100 ct	e. Shelf life:		-			24	Months
if yes, enter class #				Orphan Drug Status			OIZC.				Initial shelf life at launch	(if different):				Months
a product kit?		No		FDA 4			Strength:		60 mg			ORDER INFORM	AATION			
if yes, list NDCs of component parts				FDA Approval Status					Hard gelatin capsule			OKDEK INFORM	MATION			
reverse numbered?		No	'				Dosage Forn	n:	riara gelatiir capsule		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No] .	Allergens Present							x Bottle		1 Bottle of 1	00 Capsules		
latex-free?		Yes		Corn. Alco	hol, Animal		Product Sha	pe:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes							Agus blue opegue can and agus		Ampule		Minimum			Vee
correctional institution block? opioid?		No No	-				Product Cold	or:	Aqua blue opaque cap and aqua blue opaque body		Glass Tube		Wilnimum o	rder quantity	?	Yes
Cannabinoid?		No	-	Country of Origin	USA				Cap imprinted with 'AC' in black ink		Vial Liquid Sql					
If Unit Dose, is item bar coded to u	unit dose for		1	,			Product Impi	rint:	and body imprinted with '60' in black ink		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?				Is this product covered u	nder the						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:				Trade Agreements Act (1	ГАА)?	Yes					Vial Powder Mult Other: Write In			Inner/Carton	/Pack	
			-	OR GENERIC DRUG PR	ODUOTO						Other: write in			Case		
			F	OR GENERIC DRUG PR	ODUCIS											
						Au	thorized Generic	*If Auth	horized Generic, other		P	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB							section fields are not applicable Rec. sell unit to customer?					Rx billing unit to pharmacy:			
II. Generic Equivalent to What Brand?: Vyvanse						Each				,-						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFO							(Write-in, e.g. 1 Vial)				Gram					
		DRUG	SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	RMATION				HCPCS J-Cod	le:			Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	irer?		Yes		GLN:	0860000397957				ITE	M AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	anon or manarada			No		02	000000000000000000000000000000000000000									
If yes, select exemption:						GCP:						Dimensi	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:										'	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?				No			riginal product pure	chased		Item/Each:	0.11	1.88	1.88	3.23	11.42	1
Is product sold by manufacturer's				Yes	_	direct from n						1.00		0.20		'
Has FDA granted waiver/exception If yes, attach documentation from		roduct?		No		Provide sour	ce manufacturer fo	or repact	kaged product	Box/Carton/B Inner Pack:	undle/					
ii yes, attacii documentation iroi	III FDA.									Case:						
			GTIN A	ND HIBCC PRODUCT I	NFORMATION						2.56	12.3	8.3	3.8	387.94	24
										Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)			HIBCC		GTI	N-14		Unit of Use GTIN-14							
	N	Quantity	1 1			000	31722355018									
x Item/Each Box/Carton/Bundle/Inner Pack	N	1				003	31722333018	-			COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case	N	24				103	31722355015									
Pallet										Regular Cost			Vendor #:			
										Invoice Cost	(WAC) (\$)	\$932.00	Whsl. Code			
			-					-		An of deter	9/18/2024		Fineline Co	de:		
								-		As of date:	9/18/2024		-			
•			At	tach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE	INSER	T, LABEL AND PHOTO OF P	RODUCT PACK	GING and BARCODE.		•			
	ormation on page				, -				ated Dron Shin Only							



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? 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? No	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 b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?	EFA Hazardous waste code.						
(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? 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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: NO NO Phone: DEA #: NCPDP#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Yes Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. 2 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 Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com						
Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.						
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Pa	t 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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday						
	Priority Overnight receipt available:						
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						