

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

Version 2021					Introduction	Туре:	New Item	x	Final Version			Date:	6/23/	2024
		PRODUCT INFORM	TION						SPECIAL HAN	DLING AND STOR	RAGE REQUIR	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Applica	tion:	ANDA	a. Temperature – Indicate the USP temperature range for this product.							
									etween 20 and 25 C (68° – 77° F)					
Medical Device Class, if applicable:														
	11-856-3719							Other Te	emperature Range F	Requirement	Excursions p	permitted to 1	5° to 30° C (5	i9° to 86°F)
Proprietary Name (If Applicable) and		Lamotrigine Extended-Release Ta							rite in)					
5	31722-240-30	Unit of Use NDC CVX Code:		31722-240-30	UPC: MVX Code:	331722	240307	Notes						
UDI					MVX Code:									
Description:	Lamotrigine Extended-Release	e Tablets, USP 25 mg							oduct to be shipped				No	
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No														
Active ingredient(s). Contact for temperature excursion questions:														
URL for Additional Product Information	ation: www.camb	erpharma.com						Name:	tare executeren qu		Soma Raju			
Address:	00 Centennial Ave, Suite 1			Address 2:				Number:			732-529-0423			
	Piscataway State:			NJ		08854	Group E-mail: somaraju@heterousa.com				<u>n</u>			
					customerservice	@camber	rpharma.com							
					732-562-8788			c. Special regulations for product in any states? No Special returns requirements for this product? No						
Product Therapeutic Classification	Pnenyitriaz	zine anticonvulsant						Special	returns requirement	s for this product?			No	
	ADDITIONAL PROP	DUCT INFORMATION			PRODUCT	DESCRIE	PTION INFORMATION	d. Store product (unit o	of sale) upright?				No	
The product is?	ABBIMONALTIKOL		Direct-Ship O	nly	- I KOBOCI	BLOOKIP	Hort IN ON ANON			la) from Latro				
The product is? a legend device?	No	Is the Product Is the Product	Unit of Use				30 ct	e. Shelf life:	product (unit of sa	ie) from light?			No 24	Months
if yes, enter class #		Orphan Drug Status	5111 01 030		Size:				nelf life at launch (	f different):			24	Months
a product kit?	No				Ctronethy	2	25 mg							
if yes, list NDCs of		FDA Approval Status			Strength:	_				ORDER INFORM	IATION			
component parts					Dosage For	m: <sup>F</sup>	Film-coated tablet							
reverse numbered? co-licensed?	No	Allermene Dresent			_			Unit of S	Sale Bottle		What is the 1 Bottle of 3		unit?	
latex-free?	No Yes	Allergens Present				F	Round, biconvex	X	Box/Carton			g. 1 Box of 1	) (Vials)	
preservative-free?	Yes	Lactose, A	nimal Products		Product Sha	ape: '	tound, biconvex		Ampule		(Wine in, e.	g. 1 Dox of 1	5 1013)	
correctional institution block?	No				Product Col	1	Yellow		Glass		Minimum or	der quantity	?	Yes
opioid?	No				Product Col				Tube					
Cannabinoid?	No	Country of Origin	China		Product Imp		Printed with 'Y31' on one side in black nk and no mark on the reverse side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un	nit dose for	In this product powered							Vial Liquid Multi Vial Powder Sql				ch package t	ype?
hospital scanning? If Unit Dose, indicate NDC here:		Is this product covered Trade Agreements Act		No					Vial Powder Sgi Vial Powder Multi			Each Inner/Carton	/Pack	
il Olit Dose, indicate NDC fiele.		Hade Agreements Act	170 ():	NO					Other: Write In			Case	/i dok	
•		FOR GENERIC DRUG P	RODUCTS											
				Au	thorized Generic		orized Generic, other		PH	ARMACY 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?: Lamictal XR							Each							
(Write-in, e.g. 1 Vial) DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								Gram Milliliter						
	DRUC	SUPPLY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION				-				Milliter		
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0331722498975								ITEN	AND PACKING I	NFORMATION	N			
Is product exempt from DSCSA?		No												
If yes, select exemption:				GCP:						Dimensi	ions (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No	_		riginal product pur	chased		Item/Each:	0.12	1.5	1.5	3.75	8.44	1
Is product sold by manufacturer's Has FDA granted waiver/exception		Yes		direct from m	nfr? ce manufacturer fo	or ropool-	aged product	Box/Carton/Bundle/						
If yes, attach documentation from		110		FIOVICE SOUL		пераск	ageu product	Inner Pack:						
								Case:	24	10	7.05	4	200.00	24
		GTIN AND HIBCC PRODUCT	INFORMATION						3.4	10	7.25	4	290.00	24
								Pallet:						
Saleable Unit of Measure	Saleable Qua	Intity HIBCC			N-14		Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack	1 00331722240307 00331722240307						00331722240307	COST INFORMATION WHOLESALER USE ONLY:						
X Case	24	-		10331722240304				Regular Cost			WHOLESALER USE ONLY:			
Pallet	24										Vendor #:			
											Whsl. Code			
						_					Fineline Co	de:		
						-		As of date:	11/14/2022		4			_
											1			
<u> </u>				C) or per he	rd lattar DACKACT		, LABEL AND PHOTO OF P				Į			
*Please provide any additional info	ormation on page 2	Allach copy of SAFETY D	ATA SHEET (SD	or non naza			, LABEL AND PHOTO OF P ated Drop Ship Only.	RODUCT PACKAGING and Signatu						
r lease provide any additional info	mation on page 2.				See new p. 3 for	Designa	area brop ship Only.	Signatu						

## HDA🔾

## **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? 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? 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 Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Is the product a NIOSH hazardous drug?         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       If yes, indicate which:							
a. On/definition for holder     b. Proper Shipping Name     c. DOT Hazard Class     d. Packing Group     e. Inhalation Hazard?     Is this product regulated for shipment by IATA?     No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:							
(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?	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         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) Special Permit; DOT-SP	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:							
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No       Registry Program Contact Name:       Comments							
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS         Contact tel. # if product received damaged:       1-866-827-3647         Is product returnable for credit:       Yes							
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com							
No     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:     No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?							
MISCELLANE	OUS 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         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:       Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?