

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	6/23	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
			13949			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:														
DUNS:	11-856-3719							·	Other Temperature Range F	Requirement	Excursions p	ermitted to 1	5° to 30° C (59° to 86°F)
Proprietary Name (If Applicable) as	nd Established Na	ame: La	notrigine Extended-Release Tal	olets, USP 300	mg				(write in)	•	1			
Selling Unit NDC:	31722-245-30		Unit of Use NDC:		31722-245-30		722245302		Notes					
UDI			CVX Code:			MVX Code:								
Description: Lamotrigine Extended-Release Tablets, USP 300 mg Is this product to be shipped to customers on ice? No								1						
			, , , , , , , , , , , , , , , , , , ,						Is this product to be shipped				No	
Active Ingredient(s):		Lamotrigine, US	P								•			_
								b. Contact for	temperature excursion que	estions:				
URL for Additional Product Inform		www.camberpha	rma.com						Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway						p: 08854		Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service				customerservice@can	nberpharma.com							7	
Phone Number:	1-866-827-3647	les sur s			Fax:	732-562-8788		c. Special regulations for product in any states?					No	-
Product Therapeutic Classification	1:	Phenyltriazine a	nticonvulsant						Special returns requirement	s for this product?			No	
	4.5.5121													-
	ADDITI	ONAL PRODUCT	INFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.			Initial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	300 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		1.1				Dosage Form:	Film-coated tablet		Halt at Oak		M/hat ia tha	NDC asilias		
reverse numbered?		No	Allaurana Duasant						Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Caplet, biconvex		x Bottle Box/Carton		1 Bottle of 30 (Write-in, e.g		O \/iolo\	
preservative-free?		Yes	Lactose, An	imal Products		Product Shape:	Capiet, biconvex		Ampule		(**************************************	g. 1 DOX 01 1	o viais)	
correctional institution block?		No					Gray		Glass		Minimum or	der quantity	17	Yes
opioid?		No				Product Color:	City		Tube			uci quainity	•	103
Cannabinoid?		No	Country of Origin	China			Printed with 'Y36' on one side in black		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		, ,			Product Imprint:	ink and no mark on the reverse side		Vial Liquid Multi		If Yes, how i	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 (ΓAA)?	No				Vial Powder Multi			Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											_			
					Autl		Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sec	tion fields are not applicable	Rec. sell unit t	o customer?		Rx billing ur	nit to pharm	асу:	
II. Generic Equivalent to What Bran	nd?:	Lamictal XR										Each	-	
							-	(Write-in, e.g.	1 Vial)			Gram		
		DRUG SU	PPLY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION							Milliliter		
				_										
Does supplier meet DSCSA definit	ion of manufactu	rer?	Yes	_	GLN:	0331722498975			IIEN	I AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm	•	Volume	Saleable #
Other exemption - Write in:									.reight Ebb.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		ginal product purchas	ed	Item/Each:	0.12	1.5	1.5	3.75	8.44	1
Is product sold by manufacturer's			Yes No	_	direct from mf			- 10 1 15						
Has FDA granted waiver/exception		roduct?	INO		Provide sourc	e manufacturer for rep	раскадей ргодист	Box/Carton/Bu	ingle/					
If yes, attach documentation fron	II FDA.							Case:						
			GTIN AND HIBCC PRODUCT I	NEORMATION				Case.	3.4	10	7.25	4	290.00	24
								Pallet:						
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTIN	-14	Unit of Use GTIN-14	l anon						
X Item/Each		1				1722245302	00331722245302							
Box/Carton/Bundle/Inner Pack									COST INFORMATION		\	WHOLESAL	ER USE ONL	_Y:
X Case		24			1033	1722245309								
Pallet	_							Regular Cost			Vendor #:			
								Invoice Cost (WAC) (\$)	\$72.15	Whsl. Code			
									444440000		Fineline Cod	de:		
								As of date:	11/14/2022		ļ			
 				T. O					0000 1010000		<u> </u>			
		_	Attach copy of SAFETY DA	ATA SHEET (SE	S) or non hazar		ERT, LABEL AND PHOTO OF P	'RODUCT PACKA						
*Please provide any additional info		7				See new n 3 for Desi	ignated Drop Ship Only.		Signature:					



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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	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?	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	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
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 Phone: DEA #: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments						
ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:						
Is the Product							
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? Comments?						
MISCELLANE	DUS NOTES and/or Image of Product Barcode:						



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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? Is product order for restocking purposes?