

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

Version 2021						Introduction Typ	e: New Item		x Final Version			Date:	11/15	5/2022
			PRODUCT INFORMA	TION					SPECIAL HA	NDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharma	ceuticals, Inc.				Application	n: ANDA	a. Temperati	ure - Indicate the USP temp	erature range for	this product.			
Application Number for NDA/AN			ice):	21	3949		1	di romporati	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	82-677-4775							1	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Lamo	trigine Extended-Release Ta	blets USP 25m	a 30ct			T	(write in)	rtoquiromont				
Selling Unit NDC:	31722-240-30		Unit of Use NDC:		9	UPC: 33	31722240307	†	Notes					
UDI			CVX Code:			MVX Code:		†						
December :	Oral Calid Table	at Dayand bissaying		nnau Drintad	ith "V24" in bloo	k inte I numer No monte		ī	la this anadust to be obised		:2		No	
Description:	Oral Solid - Table	et, Round, biconvex,	film-coated tablets, Yellow, U	pper: Printed w	iui foi ili biac	KINK LOWER: NO Mark			Is this product to be shipped Is this product to be shipped				No	-
Active Ingredient(s):		Lamotrigine						+	is this product to be shippe	ed to customers on	uly ice :		INU	1
Active ingredient(s).	Active ingredient(g).						h Contact fo	or temperature excursion qu	uestions:					
URL for Additional Product Information: www.camberpharma.com						D. Contact ic	Name:	uestions.	Soma Raju					
Address:					Address 2:		+	Number:		732-529-042	23			
City:	Piscataway State: NJ Zip: 08854					Zip: 08854	Group E-mail: somaraju@h				a com			
Key Contact:	Customer Servic	e			Email:		@camberpharma.com	1	o. oup 2 main		<u>somaraja</u> (<u>ericterous</u>	<u>u.com</u>	
Phone Number:	1-866-827-3647	-			Fax:	732-562-8788	<u> </u>	c. Special re	gulations for product in an	v states?			No	1
Product Therapeutic Classification		Anticonvulsant							Special returns requiremen		,		No	1
1 Todact Therapeatic Glassification	,,,,	7 II II OO II Y GIOGIII							Openial retains requiremen	its for this product:			140	1
	ADDIT	IONAL PRODUCT IN	NFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store product (unit of sale) upright?				1		
The was dead in 0				Direct-Ship 0	Only			ar otoro prot		-l-) (l'-l-(0				4
The product is?			Is the Product	Neither	Only				Protect product (unit of s	iale) from light?			No	
a legend device?		No	Is the Product	Neurier		Size:	30ct	e. Shelf life:					24	Months
if yes, enter class #		lat.	Orphan Drug Status				25mg		Initial shelf life at launch	(if different):				Months
a product kit?		No	FDA Approval Status			Strength:	25mg			ORDER INFOR	MATION			
if yes, list NDCs of			FDA Approvai Status				Oral Solid - Tablet			ORDER INFOR	WATION			
component parts reverse numbered?		No				Dosage Form:	Oral Solid - Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 3		, unit.	
latex-free?		No	Allergens i resent				Round, biconvex, film-coat		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape:	reduid, biconvex, min coat		Ampule		(VVIIIC III, C	.g. I Dox of I	o viais)	
correctional institution block?		No					Yellow		Glass		Minimum o	rder quantity	12	Yes
opioid?		No				Product Color:	TCIIOW		Tube			raci quantit	, .	103
Cannabinoid?		No	Country of Origin	China			Upper: Printed with "Y31" in		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		,g			Product Imprint	:		Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?	u 4000 ioi	No	Is this product covered of	under the					Vial Powder Sql			Each		.,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Power Multi			Inner/Cartor	n/Pack	
				*					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS								-		
					Au	thorized Generic *It	Authorized Generic, other		Р	HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					se	ection fields are not applicable	Rec. sell uni	t to customer?		Ry hilling u	nit to pharm	acv.	
II. Generic Equivalent to What Bra		LAMICTAL XL									TO DIMING C	Each		
Gonono Equivalent to Tinat Bio								(Write-in, e.g	ı. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION			(, , , , ,	,,			Milliliter		
Does supplier meet DSCSA defin	ition of manufactu	irer?	Yes		GLN:	0331722000000			ITE	M AND PACKING	INFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:			1	141-1-1-1	Dimens	sions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:								_	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product purcha	sed	Item/Each:	0.1		1.5	3.75		1
Is product sold by manufacturer's	s exclusive distrib	utor?	Yes		direct from m	nfr?					1.5	3.75		'
Has FDA granted waiver/exception		roduct?	No	_[Provide sour	ce manufacturer for re	epackaged product	Box/Carton/	Bundle/					
If yes, attach documentation fro	m FDA.							Inner Pack:						
								Case:	24	12	9	4		24
		GT	IN AND HIBCC PRODUCT I	NFORMATION										
								Pallet:						
Saleable Unit of Measure	:	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each		1			003	31722240307	10331722240304	1	COST INFORM TION			WHOI FOAL	ER USE ONL	V.
Box/Carton/Bundle/Inner Pack		24			100	24722240224			COST INFORMATION			WHOLESAL	ER USE UNL	.17.
X Case		24			103	31722240304		l Barrelle C			Vander #			
Pallet								Regular Cos		***	Vendor #:	ш.		
	_							Invoice Cost	(VVAC) (\$)	\$21.06	Whsl. Code			
								An of date			Fineline Co	ue:		
								As of date:			-			
 			Attach convert SAFETY D	ATA SHEET (SI	DS) or non hors	rd letter DACKACE IN	SERT, LABEL AND PHOTO OF I	DDUDITOT BACK	ACING and BARCODE		-			
*Please provide any additional in	formation on noon	. 2	, macri copy of SAFETT Di	VIA OLIEET (SI	o non naza		signated Drop Ship Only.	I NODUCI FACK	Signature:					
provide any additional in	mation on page	· - ·				200 HOW P. 3 101 DE	orgraded brop only only.		o.g.iataio.					



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For Designated Drop Ship Only Products, Please Use Page 3

M.A.	ATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
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?	x Organic Inorganic Steroid/Androgen	Corrosive Oxidizer 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 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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group		Hazardous Waste Identification				
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	REMS of	REMS or REGISTRY RESTRICTIONS			
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group		Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No			
e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo	No No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
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? (if yes, identify method below)		REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name:	No	Phone: DEA #:		
Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP		Site Enrollment Number assigned by Supplier: Comments		NCPDP#: NPI #:		
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		Registry:	No			
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:		
Is the Product Controlled Substance? No Controlled Substance Code		RI	ETURN INSTRUCTIONS			
Controlled by State(s)? ARCOS Reportable? Schedule No. No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes			
CLASS OF TRADE RESTRICTION:	Yes	URL/Link to returns policy:	ruigo @gombornbormo.com			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only:	No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	product in certain states? No If so, which states? Other requirements? Comments?					
Comments:						
M	ISCELLANEC	US 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 fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:				
F	Name: Phone:	Ships regular ground for 3-10 days receipt:				
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order:		Overnight receipt available:				
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Infor	rmation Required to Process 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?				
Mis	scellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				