

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

Version 2021					Introduction Ty	pe: New Item	x	Final Version			Date:	5/18/	/2022
		PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOP	RAGE REQUIR	REMENTS*		
Company Name: Camber Pharmaceuticals. Inc.					Applicatio	on: ANDA	a. Temperature – Indicate the USP temperature range fo			this product.			
Application Number for NDA/ANI	DA/BLA (drug); PMA/510(k)(r	ned device):	2159	39		i		ature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:													
DUNS:	82-677-4775						Other T	emperature Range	Requirement				
Proprietary Name (If Applicable) and		Oxcarbazepine Tablets 600mg 10					(v	rite in)					
Selling Unit NDC:	31722-025-01	Unit of Use NDC	:			331722025010	Notes						
UDI		CVX Code:			MVX Code:								
Description:	Oral solid, tablet, oval shape	d, brown, Lower punch 'V' and Upper	Punch'7' '8'				Is this p	roduct to be shippe	d to customers on i	ce?		No	]
							Is this p	roduct to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s):	Oxcarbaz	epine											
URL for Additional Product Inform							b. Contact for tempera	ature excursion qu	estions:	Soma Raju			
Address:	1031 Centennial Ave (and) 8	00 Contonnial Ave. Suite 1			Address 2:		Name: Numbe			50ma Raju 732-529-042	2		
City:	Piscataway	oo Centenniai Ave, Suite 1		State:		Zip: 08854	Group			somaraju		com	
Key Contact:	Customer Service					customerservice@camberpharma.com				somulajueneterousu.com			
Phone Number:	1-866-827-3647			Fax:	732-562-8788	<u> </u>	c. Special regulations	for product in any	states?			No	1
Product Therapeutic Classification	1:						Special	returns requirement	ts for this product?			No	
													1
	ADDITIONAL PRC	DUCT INFORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store product (unit	of sale) upright?				No	]
The product is?		Is the Product	Direct-Ship Onl	ly			Protect	product (unit of sa	ale) from light?			No	1
a legend device?	No	Is the Product	Neither		Size:	100ct	e. Shelf life:						Months
if yes, enter class #		Orphan Drug Status			3128:		Initial s	helf life at launch (	if different):				Months
a product kit?	No				Strength:	600mg							
if yes, list NDCs of		FDA Approval Status			onongan				ORDER INFORM	MATION			
component parts					Dosage Form:	Oral Solid - Tablet							
reverse numbered? co-licensed?	No	Allergens Present					Unit of	Bottle		What is the 1 bottle of 10		unit?	
latex-free?	Yes	Allergens Fresent				Oval		Box/Carton			g. 1 Box of 1	) Viale)	
preservative-free?	Yes	_			Product Shap	e:		Ampule		(write iii, e.	g. 1 Dox 01 1	5 viais)	
correctional institution block?					Des los Color	Brown		Glass		Minimum or	der quantity	?	Yes
opioid?	No				Product Color	•		Tube					
Cannabinoid?	No	Country of Origin	India		Product Impri	Lower punch 'V' and Uppe		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u					r roudet impri			Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?	No	Is this product covered						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (	TAA)?	No				Vial Power Multi			Inner/Cartor	/Pack	
		FOR GENERIC DRUG PF						Other: Write In			Case		
		FOR GENERIC DRUG PR	CODUCTS										
			Γ	Au	thorized Generic	*If Authorized Generic, other		Ph	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB		_			section fields are not applicable	Rec. sell unit to custo			Rx billing u	nit to phorm	201/2	
I. Generic Equivalent to What Bran							Nec. sen unit to custo		1	KX billing u	Each	icy:	
							(Write-in, e.g. 1 Vial) Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							( ,				Milliliter		
Does supplier meet DSCSA definit	ion of manufacturer?	Yes		GLN:	0331722000000			ITEN	I AND PACKING II	NFORMATION	N		
Is product exempt from DSCSA?		No											
If yes, select exemption:				GCP:				Weight Lbs.		ions (US msm		Volume	Saleable #
Other exemption - Write in:		N1-		_					Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	ovolucius distributor2	No			iginal product		Item/Each:	0.25		2.25	4	0	1
Is product sold by manufacturer's Has FDA granted waiver/exception		NO			rect from mfr?	repackaged product	Box/Carton/Bundle/						
If yes, attach documentation from			F	i ovide sourc		repuerageu product	Inner Pack:					0	
							Case:		10.75	10		0	
		GTIN AND HIBCC PRODUCT	INFORMATION					7.2	13.75	10	5.25	0	24
							Pallet:					0	
Saleable Unit of Measure	Saleable Qu	antity HIBCC			N-14	Unit of Use GTIN-14						0	
X Item/Each	1			003	31722025010								
Box/Carton/Bundle/Inner Pack							COS	ST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case	24			203	31722025014		Bogular			Vonder #			
Pramet							Regular Invoice Cost (WAC) (\$	3	00.00	Vendor #: Whsl. Code	<b>#</b> •		
								<i>''</i>	φου.υυ	Fineline Code			
							As of date:						
		Attach copy of SAFETY D	ATA SHEET (SDS	) or non haza	rd letter, PACKAGE I	NSERT, LABEL AND PHOTO OF	PRODUCT PACKAGING ar	nd BARCODE.		-			
*Please provide any additional info	ormation on page 2.				See new p. 3 for D	esignated Drop Ship Only.	Signatu	ıre:					

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

Version 2021 Fo	Designated Drop Ship Only Products, Please Use Page 3					
MAT	RIAL 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? c. Contact Hazard? d. Does this product require special clean-up instructions?	X       Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       Image: Contact Hazard					
(If yes, attach SDS with special instructions.)         e. Does the product contain DEHP?         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?     No       If yes, indicate which:     No					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification No EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? (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 REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL: No					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No	No     Med Guide Required       Limited Distribution Requirement     Imited Distribution Requirement       Comments / Details: (For example, iPledge program?)     Imited Distribution       REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Imited Distribution					
Is this product shipped utilizing an authorized DOT exception or Special Permit? (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);	Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:					
SP# ADD'L STORAGE INFORMATION	Registry:     No       Registry Program Contact Name:     Phone:       Comments     Phone:					
Controlled Substance?       No       Controlled Substance Code         Controlled by State(s)?       No       Listed Chemical (List I or II)         ARCOS Reportable?       No       If yes, indicate which:         Schedule No.       Is it a scheduled listed chemical product?:         CLASS OF TRADE RESTRICTION:	No     RETURN INSTRUCTIONS       No     Contact tel. # if product received damaged:     1-866-827-3647       No     Is product returnable for credit:     Yes       URL/Link to returns policy:     Ves					
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)	Yes     contact - customerservice@camberpharma.com       No     Special regulations or returns requirements for this product in certain states?       No     If so, which states? Other requirements? Comments?					
Comments: MIS	ELLANEOUS 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?