

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

Version 2021						Introduction Type:	New Item		x Final Version			Date:	5/18	3/2022
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperatu	ire - Indicate the USP tempe	erature range for t	his product.			
Application Number for NDA/AN	IDA/BLA (drug); PN	IA/510(k)(med devi	ice):	215	939				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica								1						
DUNS:	82-677-4775								Other Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		me: Oxca	rbazepine Tablets 300mg 10					I	(write in)					
Selling Unit NDC:	31722-024-01		Unit of Use NDC:				722024013		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Oral solid, tablet, o	oval shaped, brown,	, Lower punch 'V' and Upper	Punch'7' '7'				I	Is this product to be shipped	d to customers on i	ce?		No	
									Is this product to be shipped	d to customers on	dry ice?		No	
Active Ingredient(s):		Oxcarbazepine												
	_							b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform		(1) 000 01-	and the Arman Coultry 4			A ddunen O.		-	Name:		Soma Raju	20		
Address: City:	Piscataway	ve (and) 800 Cente	enniai Ave, Suite 1		State:	Address 2:	: 08854		Number: Group E-mail:		732-529-042	23 @heterousa	. com	
Key Contact:	Customer Service				Email:		camberpharma.com		Group E-mail.		Sumaraju	wheterouse	a.com	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	Lamber pharma.com	c Special re	gulations for product in any	states?			No	7
Product Therapeutic Classification								or openiar re	Special returns requirement				No	
l round morapound diagonicum	•••								opoolal rotarrio roquirorriorri	io for ano product.				
	ADDITIO	ONAL PRODUCT IN	NFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit of sa	ala) from light?			No	1
a legend device?		No	Is the Product	Neither	y		100ct	e. Shelf life:	Frotect product (unit of Sa	ile) iroin light?			INU	Months
if yes, enter class #		140	Orphan Drug Status			Size:	10001	c. onen me.	Initial shelf life at launch (if different):				Months
a product kit?		No				a	300mg							
if yes, list NDCs of			FDA Approval Status			Strength:	,			ORDER INFOR	MATION			
component parts						Dosage Form:	Oral Solid - Tablet							
reverse numbered?		No				Dosage Form.			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 1			
latex-free?		Yes				Product Shape:	Oval		Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				-	D		Ampule					V
correctional institution block? opioid?		No				Product Color:	Brown		Glass Tube		Minimum o	rder quantity	11	Yes
Cannabinoid?		No	Country of Origin	India			Lower punch 'V' and Upper		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	Country of Origin	maia		Product Imprint:	Lower parion v and oppor		Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?	ann 4000 101	No	Is this product covered of	under the					Vial Powder Sql			Each		.,,,,,
If Unit Dose, indicate NDC here:		·	Trade Agreements Act (TAA)?	No				Vial Power Multi			Inner/Cartor	/Pack	
			_	L					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											_			
					Au		uthorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sect	ion fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	ınd?:	Trileptal										Each		
								(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPP	PLY CHAIN SECURITY ACT	(DSCSA) INFORI	MATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	or?	Yes		GLN:	0331722000000			ITEN	I AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	ition of manufactur	GI:	No	_	GLIV.	0331722000000				I AND I ACITING I	NI OKIMATIO			
					CCD.			1		Dime	ione (IJS man	nte \	Value -	Calastii e
If yes, select exemption: Other exemption - Write in:					GCP:				Weight Lbs.	Dimens Depth	ions (US msn Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yos was or	iginal product		Item/Each:		Deptii	1			
Is product sold by manufacturer's	exclusive distribu	tor?	No			rect from mfr?		Aciii/Lucii.	0.15		1.625	3.375	0	1
Has FDA granted waiver/exceptio			No			ce manufacturer for rep	ackaged product	Box/Carton/E	Bundle/				0	
If yes, attach documentation fro	m FDA.							Inner Pack:					0	
								Case:	4.45	11.75	8.5	4.5	0	24
		GT	TIN AND HIBCC PRODUCT I	NFORMATION					0		0.0			
Onlankin Hall of Manager	_							Pallet:					0	
Saleable Unit of Measure	S	aleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31722024013			COST INFORMATION			WHOLESAL	ER USE ONL	γ.
X Case		24			303	31722024017			JOST INI OKWATION			WHOLLSAL	EK-OSE ONE	-1
Pallet		24			203	5ZZ0ZT011		Regular			Vendor #:			
								Invoice Cost	(WAC) (\$)	\$55.00	Whsl. Code	#:		
]]		\$22.00	Fineline Co			
								As of date:						
								11						
μ								Ц			1			
			Attack copy of CAEETY D	ATA SHEET (SDS	S) or non haza	rd letter DACKAGE INISE	RT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE.					
*Please provide any additional inf			Allacir copy of SAFETT D	ATA STILLT (SDC) or norriuza		gnated Drop Ship Only.		Signature:					



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?	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? 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	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)	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? (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#: 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 Is the Product	Comments						
Controlled Substance? 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	Contact tel. # if product received damaged: Is product returnable for credit: 1-866-827-3647						
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail charmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
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: No	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments) Comments:	If so, which states? Other requirements? Comments?						
MISOFILA	ISOUS NOTES and/or Image of Dradust Parenday						
MISCELLA	NEOUS 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 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?