

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

Version 2021						Introduction T	Гуре:	New Item		x	inal Version			Date:	5/18	/2022
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUIR	REMENTS*		
Company Name:	Camber Pharmaceuti	cals. Inc.				Applicat	tion:	ANDA	a. Temperatu	re – Indicat	e the USP temp	erature range for the	his product.			
Application Number for NDA/ANI			ce):	21	5939				ui romporata	Temperatu		Controlled Room -	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applicab			,								5					
DUNS:	82-677-4775								L	Other Terr	perature Range I	Requirement				
Proprietary Name (If Applicable) a	nd Established Name	: Oxcar	bazepine Tablets 150mg 10							(write	e in)					
Selling Unit NDC:	31722-023-01		Unit of Use NDC:			UPC:	331722023	016		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Oral solid, tablet, ova	I shaped, brown,	Lower punch 'V' and Upper	Punch'7' '6'								d to customers on id			No	
Is this product to be shipped to customers on dry ice? No																
Active Ingredient(s): Oxcarbazepine b. Contact for temperature excursion questions:																
UDI for Additional Draduat Inform	ation.								b. Contact for	r temperatu Name:	re excursion qu	estions:	Come Daiu			
URL for Additional Product Inform Address:	1031 Centennial Ave	(and) 900 Canto	anial Ava. Suita 1			Address 2:				Name: Number:			Soma Raju 732-529-042	2		
City:	Piscataway	(and) 000 Center	Inidi Ave, Suite 1		State:	NJ	Zip: 08	854		Group E-r	nail·		somaraju@		com	
Key Contact:	Customer Service Email:				customerservice@camberpharma.com			0.0up = 1			Jonarajae					
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	ulations fo	r product in any	states?			No	1
Product Therapeutic Classification	n:									Special re	turns requirement	s for this product?			No	
-										1						
	ADDITION	AL PRODUCT IN	FORMATION			PRODUCT I	DESCRIPTIC	ON INFORMATION	d. Store prod	uct (unit of	sale) upright?				No	
The product is?			Is the Product	Direct-Ship 0	Dnly					Protect pr	oduct (unit of sa	le) from light?			No	1
a legend device?	No	D	Is the Product	Neither		Size:	1000	ct	e. Shelf life:							Months
if yes, enter class #			Orphan Drug Status			UILC.				Initial she	lf life at launch (if different):				Months
a product kit?	No	D				Strength:	150	mg								
if yes, list NDCs of component parts			FDA Approval Status				Oral	Solid - Tablet				ORDER INFORM	IATION			
reverse numbered?	No					Dosage Form	m: Oral	Solid - Tablet		Unit of Sa	lo		What is the	NDC selling	unit?	
co-licensed?	No		Allergens Present								Bottle		1 bottle of 10		unit.	
latex-free?	Ye		/ liei gone i rocont				Ova				Box/Carton		(Write-in, e.g		0 Vials)	
preservative-free?	Ye	es				Product Sha	ipe:				Ampule		(··· /··	5	,	
correctional institution block?						Product Cold	Brov	wn			Slass		Minimum or	der quantity	?	Yes
opioid?	No					i roduct ook					ube					
Cannabinoid?	No	D	Country of Origin	India		Product Imp	rint:	er punch 'V' and Uppe			/ial Liquid Sgl					
If Unit Dose, is item bar coded to u hospital scanning?	nit dose for		la this are duct sourced .			-					/ial Liquid Multi /ial Powder Sal		If Yes, how 24	many of whi Each	ch package	type?
If Unit Dose, indicate NDC here:	INC)	Is this product covered of Trade Agreements Act (No						/ial Powder Sql /ial Power Multi			Each Inner/Cartor	Pack	
il Onit Dose, indicate NDC here.			Thate Agreements Act (170 ():	NO						Other: Write In			Case	/I dok	
			FOR GENERIC DRUG PR	ODUCTS												
					Au	thorized Generic		ed Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section field	ds are not applicable	Rec. sell unit	to custome	er?		Rx billing ur	nit to pharm	acy:	
II. Generic Equivalent to What Brand?: Trileptal							Each									
(Write-in, e.g. 1 Vial) Gram																
		DRUG SUPPI	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION				_					Milliliter		
Does supplier meet DSCSA definit	ion of manufacturer?		Yes		GLN:	0331722000000					ITEA	I AND PACKING I		·		
Is product exempt from DSCSA?			No	-	JEN.	0001122000000										
If yes, select exemption:					GCP:							Dimensi	ons (US msm	uts)	Volume	Saleable #
Other exemption - Write in:					J UI .						Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	iginal product			Item/Each:		0.1		1.625	3.125	0	1
Is product sold by manufacturer's	exclusive distributor	?	No			rect from mfr?					0.1		1.625	3.125	0	1
Has FDA granted waiver/exception	n/exemption for produ		No		Provide sour	ce manufacturer fo	or repackage	ed product	Box/Carton/B	undle/					0	
If yes, attach documentation from	n FDA.								Inner Pack:							
		0.1	N AND HIBCC PRODUCT I	NEORMATION					Case:		3	10	7.125	4.65	0	24
		GI	IN AND HIBCC PRODUCT I	NFORMATION					Pallet:							
Saleable Unit of Measure	Sale	able Quantity	HIBCC		GTI	N-14	Un	it of Use GTIN-14	ranet.						0	
X Item/Each		1				31722023016			L			1			1	
Box/Carton/Bundle/Inner Pack							COST INFORMATION				WHOLESALER USE ONLY:					
X Case		24			203	31722023010										
Pallet	, –								Regular				Vendor #:			
	_				_		-		Invoice Cost	(WAC) (\$)		\$30.00	Whsl. Code			
	-				-		-		As of date:				Fineline Coo	de:		
	-				_		-		AS OF DATE:							
<u> </u> +			Attach copy of SAFETY D	ATA SHEET (SI)S) or non haza	rd letter, PACKAGE			RODUCT PACKA	GING and	BARCODE					
*Please provide any additional info	ormation on page ?		, main copy of OAT LIT D		co, or non nd2d	See new p. 3 for				Signature						

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:						



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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?