

						Introduction T	ype: New Item		x Final Version			Date:	1/11/	/2024
			PRODUCT INFORMA	TION					SPECIAL HANI	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmaceutic	cals, Inc.				Applicat	tion: ANDA	a. Temperatu	ure - Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/AN	IDA/BLA (drug); PMA/5	10(k)(med device	e):	214	4571			•	Temperature Range	Controlled Room -	between 20	and 25 C (68°	– 77° F)	
Medical Device Class, if applica	ble:													
DUNS:	11-856-3719								Other Temperature Range R	equirement	Excursions p	ermitted to 1	5° to 30° C (5	9° – 86° F)
Proprietary Name (If Applicable) a		Varenic	cline Tablets 0.5 mg						(write in)					
Selling Unit NDC:	31722-678-56		Unit of Use NDC:		31722-678-56	UPC:	331722678568		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Varenicline Tablets 0.5	5 mg							Is this product to be shipped	to customers on ic	e?		No	1
									Is this product to be shipped	to customers on d	ry ice?		No	1
Active Ingredient(s):	Var	renicline												
								b. Contact fo	or temperature excursion que	stions:				
URL for Additional Product Inform		vw.camberpharma.c							Name:		Soma Raju			
Address:	1031 Centennial Ave (	and) 800 Centenn	nial Ave, Suite 1		Ctata	Address 2:	7	_	Number:		732-529-042			
City:	Piscataway Customer Service				-	Zip: 08854 @camberpharma.com	Group E-mail: somaraju@heterousa.com			<u>L</u>				
Key Contact: Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u>scamberphama.com</u>	C Special rea	gulations for product in any	states?			No	I
Product Therapeutic Classification		cotinic receptor par	urtial agonist		- I ux.	702 002 0700		C. Opeciai reg	Special returns requirements				No	1
Froduct Therapeutic Classification	III.	Journa receptor par	rtiai agoriist						Special returns requirements	i ioi tiiis pioduct:			140	I .
	ADDITIONA	AL PRODUCT INF	ORMATION			PRODUCT	DESCRIPTION INFORMATION	d Store prod	duct (unit of sale) upright?				No	I
The need heat in 0	7.55.11.61.7.			Direct-Ship O	)nlv	1 1105001		u. otore proc		-) ( l'l-10				i
The product is?	No		Is the Product	Unit of Use	Jilly		56 ct	e. Shelf life:	Protect product (unit of sa	e) from light?			No 24	Months
a legend device? if yes, enter class #	INO		Orphan Drug Status	Offit of Ose		Size:	56 Ct	e. Shell life:	Initial shelf life at launch (i	different):			24	Months
a product kit?	No	,	Orphan Drug Status				0.5 mg		initial shell life at launch (i	umerent).				WIOTILITS
if yes, list NDCs of	110		FDA Approval Status			Strength:	g			ORDER INFORM	ATION			
component parts						Dosage Form	Film coated tablet							
reverse numbered?	No	,				Dosage Form	"-		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	No		Allergens Present						x Bottle		1 Bottle of 56			
latex-free?	Yes		Alc	ohol		Product Sha	pe: Capsular, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 10	Vials)	
preservative-free?	Yes								Ampule					
correctional institution block?						Product Cold	Pink		Glass		Minimum or	der quantity	?	Yes
opioid? Cannabinoid?	No		Country of Origin	India			Debossed with "H" on one	-	Tube					
If Unit Dose, is item bar coded to	No unit does for		Country of Origin	india		Product Imp	rint: side and "V23"	<b>'</b>	Vial Liquid Sgl Vial Liquid Multi		If Yes, how i	nany of whi	ch nackago	tune?
hospital scanning?	Jill dose for		Is this product covered u	inder the			on the other side.		Vial Powder Sql			Each	ii package i	.ype:
If Unit Dose, indicate NDC here:			Trade Agreements Act (		No				Vial Power Multi			Inner/Carton	Pack	
iii ciiii 2000, iiialoalo 1120 11010.			]	,.	110			-	Other: Write In			Case	· uon	
			FOR GENERIC DRUG PR	ODUCTS										
	1			,							l			
					Aut	norized Generic	*If Authorized Generic, other		PH.	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:							section fields are not applicable	Rec. sell unit	t to customer?		Rx billing ur	it to pharma	cv:	
	AB												-,-	
II. Generic Equivalent to What Bra	AB and?: Cha	nantix							r to duotomor .			Each		
II. Generic Equivalent to What Bra		antix						(Write-in, e.g				Each Gram		
II. Generic Equivalent to What Bra			Y CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION			(Write-in, e.g						
	and?: Cha	DRUG SUPPLY						(Write-in, e.g	j. 1 Vial)			Gram Milliliter		
Does supplier meet DSCSA defini	and?: Cha	DRUG SUPPLY	Yes		RMATION GLN:	0331722000000		(Write-in, e.g	j. 1 Vial)	AND PACKING IN		Gram Milliliter		
Does supplier meet DSCSA defini	and?: Cha	DRUG SUPPLY			GLN:	0331722000000		(Write-in, e.g	j. 1 Vial)		IFORMATION	Gram Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	and?: Cha	DRUG SUPPLY	Yes			0331722000000		(Write-in, e.g	g. 1 Vial) ITEM	Dimensio	IFORMATION	Gram Milliliter	Volume	Saleable #
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?: Cha	DRUG SUPPLY	Yes No		GLN: GCP:				j. 1 Vial)		IFORMATION	Gram Milliliter	Volume (Cube)	Saleable #
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: Cha	DRUG SUPPLY	Yes No		GLN: GCP: If yes, was ori	ginal product pure	chased	(Write-in, e.g	g. 1 Vial) ITEM	Dimensio	IFORMATION	Gram Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	and?: Cha	DRUG SUPPLY	Yes No No Yes		GLN: GCP: If yes, was ori	ginal product pure		Item/Each:	(J. 1 Vial)  ITEM  Weight Lbs.  0.069	Dimensio Depth	DONE (US msm Width	Gram Milliliter ts.) Height	(Cube)	Pieces
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	and?: Characteristic	DRUG SUPPLY	Yes No		GLN: GCP: If yes, was ori	ginal product pure	chased repackaged product	Item/Each: Box/Carton/E	(J. 1 Vial)  ITEM  Weight Lbs.  0.069	Dimensio Depth	DONE (US msm Width	Gram Milliliter ts.) Height	(Cube)	Pieces
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	and?: Characteristic	DRUG SUPPLY	Yes No No Yes		GLN: GCP: If yes, was ori	ginal product pure		Item/Each: Box/Carton/E Inner Pack:	Weight Lbs.  0.069  Bundle/	Dimension Depth 1.5	DOIS (US msm Width	Gram Milliliter ts.) Height	(Cube) 5.625	Pieces 1
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	and?: Chamber of manufacturer?  s exclusive distributor? on/exemption for production FDA.	PRUG SUPPLY  7  GTIN  able Quantity  1	Yes No No Yes No No A AND HIBCC PRODUCT II		GLN: GCP: If yes, was oridirect from mf Provide source GTIM 0033	ginal product pure r? e manufacturer fo	r repackaged product  Unit of Use GTIN-14	ltem/Each: Box/Carton/E Inner Pack: Case:	Weight Lbs.  0.069  Bundle/	Dimension Depth 1.5	DOTS (US msm Width 1.5	Gram Milliliter  tts.) Height 2.5	(Cube) 5.625	1 24
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# **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? 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?	SDS Hazard Classification  x Organic Corrosive Oxidizer Inorganic 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?  Is this product regulated for shipment by DOT?	identify NFPA Storage Level: NFPA Storage Level:  Is the product a NIOSH hazardous drug?  No					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	If yes, indicate which:  Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	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?	REMS or REGISTRY RESTRICTIONS  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#:  NCPDP#:  NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No					
<del></del>	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product Controlled Substance? No Controlled Substance Code	RETURN 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  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  1-866-827-3647  Yes					
	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Ye	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No.						
Comments:						
MISCELL	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?