

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

Version 2021						Introduction T	ype:	New Item		x Fir	nal Version			Date:	1/11	/2024
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214571							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:																
DUNS:	11-856-3719									Other Tempe	erature Range F	Requirement	Excursions p	permitted to 1	5° to 30° C (	59° – 86° F)
Proprietary Name (If Applicable) a		me: Varer	nicline Tablets 1 mg							(write i	n)					
Selling Unit NDC:	31722-679-56		Unit of Use NDC:		31722-679-56		331722	2679565		Notes						
UDI			CVX Code:			MVX Code:			l I							
Description:	Varenicline Table	ts 1 mg								Is this produ	ct to be shipped	d to customers on ic	ce?		No	
Is this product to be shipped								d to customers on d	ry ice?		No					
Active Ingredient(s): Varenicline										_	_					
IIDI for Additional Product Information							b. Contact fo	or temperature Name:	excursion qu	estions:	Soma Raju					
URL for Additional Product Information: <a href="https://www.camberpharma.com">www.camberpharma.com</a> Address: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:			Number:				732-529-042	23				
City:	y: Piscataway State: N				NJ	Zin.	08854		Group E-ma	ail·			neterousa.cor	n		
Key Contact:	Customer Service															
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special re	gulations for p	product in any	states?			No	
Product Therapeutic Classification	n:	Nicotinic receptor	partial agonist						1	Special retur	rns requirement	s for this product?			No	
Openational deliverage and the production of the																
	ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT D	DESCRIF	PTION INFORMATION	d. Store prod	duct (unit of sa	ale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only					Protect prod	duct (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:		56 ct	e. Shelf life:	•	•	, •			24	Months
if yes, enter class #			Orphan Drug Status			Size.				Initial shelf	life at launch (	if different):				Months
a product kit?		No				Strength:	1	1 mg								
if yes, list NDCs of			FDA Approval Status				-	=				ORDER INFORM	IATION			
component parts reverse numbered?		N.				Dosage Form	n: '	Film coated tablet		Unit of Sale			What is the	NDC colling	unit?	
co-licensed?		No No	Allergens Present							x Bo			1 Bottle of 5		unit:	
latex-free?		Yes					(	Capsular, biconvex			x/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Ald	cohol		Product Shap	pe:	,			npule		(	3		
correctional institution block?		No				Product Colo		Yellow		Gla	ass		Minimum or	rder quantity	?	Yes
opioid?		No				Froduct Colo	".			Tu	be					
Cannabinoid?		No	Country of Origin	India		Product Impr		Debossed with "H" on one			al Liquid Sgl					
If Unit Dose, is item bar coded to u	ınit dose for						\$	side and "V24"			al Liquid Multi				ch package	type?
hospital scanning?			Is this product covered to Trade Agreements Act (		No		ľ	on the other side.			al Powder Sql al Power Multi			Each Inner/Cartor	/Deels	
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)!	INO						her: Write In			Case	/Pack	
			FOR GENERIC DRUG PR	CODUCTS		<u> </u>								Joaco		
			TOR GENERIO BROOT	.000010												
					Aut	horized Generic	*If Auth	norized Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section	fields are not applicable	Rec. sell uni	it to customer	?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	nd?:	Chantix										1		Each	,	
		-							(Write-in, e.g	g. 1 Vial)		-		Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION									Milliliter		
Does supplier meet DSCSA definit		2	Yes	_	GLN:	0331722000000					ITEN	I AND PACKING IN	JEORMATION	N		
Is product exempt from DSCSA?	tion of manufactur	err	No	-	GLN:	0331722000000					IIEW	I AND FACKING II	NFORWATIO	N.		
					CCD.				1			Dimensi	ons (US msm	nte \	V-I	Calastic "
If yes, select exemption: Other exemption - Write in:					GCP:				1		Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If ves was ori	ginal product purc	hased		Item/Each:			1			I	
Is product sold by manufacturer's	exclusive distribu	itor?	Yes		direct from mi						0.08	1.5	1.5	2.5	5.625	1
Has FDA granted waiver/exception			No		Provide source	e manufacturer for	r repack	kaged product	Box/Carton/I	Bundle/						
If yes, attach documentation from	m FDA.								Inner Pack:							
									Case:		2.5	9.5	6.6	4	250.8	24
		GI	IN AND HIBCC PRODUCT I	NFORMATION					Pallet:							
Saleable Unit of Measure	c	Saleable Quantity	HIBCC		GTIN	1.1.4		Unit of Use GTIN-14	Pallet:							
X Item/Each	3	1	ПІВСС			1722679565	1	00331722679565								
Box/Carton/Bundle/Inner Pack										COST_IN	IFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			2033	1722679569	1									
Pallet	_								Regular Cos	st			Vendor #:			
									Invoice Cost	t (WAC) (\$)		\$207.78	Whsl. Code			
									1		14/0004		Fineline Co	de:		
									As of date:	1/1	1/2024		Į.			
<del> </del>			Attach conv of SAEETV D	ATA SHEET (SI	OS) or non hazor	d letter PACKACE	INSERT	T, LABEL AND PHOTO OF P	BUDITICE BYCK	(AGING and P/	ARCODE					
*Please provide any additional info	ormation on page	2.	, maon dopy of OAI LIT Di	OIILLI (OI	o non nazal			ated Drop Ship Only.		Signature:	OODL.					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD 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?	SDS Hazard Classification  Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?	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 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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA?	EPA Hazardous Waste Code:	Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS o	REGISTRY RESTRICTIONS					
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 Passenger & Cargo	No No	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#: NPI #:			
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		Comments  Registry:	No				
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:			
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  No Listed Chemical (List I or II)	No	R	ETURN INSTRUCTIONS				
ARCOS Reportable?  Schedule No.  If yes, indicate which: Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:		Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:	1-866-827-3647 Yes				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes		rvice@camberpharma.com				
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states?  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 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?