

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

Version 2021						Introduction	Туре:	New Item		0000	Final Version			Date:	6/1/2	2024
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*										
Company Name: Camber Pharmaceuticals, Inc.				Applica	Application: 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 applicat	ble:															
DUNS:	11-856-3719										perature Range F	Requirement	Excursions	permitted to 1	15° to 30° C (5	59° – 86° F)
Proprietary Name (If Applicable) a		ame: Vare	enicline Tablets 0.5 mg & 1 mg							(write	e in)					
Selling Unit NDC: UDI	31722-690-31		Unit of Use NDC: CVX Code:		31722-690-31	UPC: MVX Code:	33172	2690317		Notes						
Description:  Varenicline Tablets 0.5 mg & 1 mg  Is this product to be shipped to customers on ice?  Is this product to be shipped to customers on dry ice?  No																
Active Ingredient(s):  Is this product to be shipped to customers on dry ice?  No  Varenicline tartrate																
b. Contact for temperature excursion questions:																
URL for Additional Product Information: <a href="https://www.camberpharma.com">www.camberpharma.com</a>								Name: Soma Raju								
Address: 800 Centennial Ave, Suite 1					Address 2:			Number:				732-529-042				
City:	Piscataway State:				NJ		08854	Group E-mail: somaraju@heterousa.com					<u>m</u>			
Key Contact: Phone Number:	1-866-827-3647	stomer Service Email: 866-827-3647 Fax:				customerservice@camberpharma.com 732-562-8788			a Special re-	aulations fo	r product in any	ctotoc?			No	ı
					l ax.	732-302-0700			c. Special regulations for product in any states?							
Froduct Therapeutic Classification	Product Therapeutic Classification:  Nicotinic receptor partial agonist  Nicotinic receptor partial agonist  No															
	ADDITI	IONAL PRODUCT I	INFORMATION			PRODUCT	DESCRI	IPTION INFORMATION	d. Store prod	duct (unit of	sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only						oduct (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use	,			53 ct	e. Shelf life:	i rotect pi	oddot (unit 01 Sa	ic, iioiii ligiit?			24	Months
if yes, enter class #		11.12	Orphan Drug Status			Size:				Initial she	If life at launch (i	if different):				Months
a product kit?		No				Strength:		0.5 mg & 1 mg								
if yes, list NDCs of						ou chigan.				ORDER INFORMATION						
component parts reverse numbered?		la.				Dosage For	m:	Film coated tablets		Unit of Sa	la.		What is the	NDC selling	mit2	
co-licensed?		No No	Allergens Present								ie Bottle		1 Carton of		unitr	
latex-free?	You				Bara da cara Oba		Capsular, biconvex			Box/Carton		(Write-in, e.g. 1 Box of 10 Vials)				
preservative-free?		Yes	Alc	ohol		Product Shape:			Ampule				, ,,,,,			
correctional institution block?		No				Product Col	or:	**See Note** 0.5 mg -			Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				110000000	Pink, 1 mg - Yellow Tube									
Cannabinoid?		No	Country of Origin	India		Product Imp	orint:	**See Note** 0.5 mg - 'H' & 'V23', 1 mg - 'H' & 'V24'			/ial Liquid Sgl /ial Liquid Multi		If Voc. how	many of wh	ioh naakaga	huno?
If Unit Dose, is item bar coded to un hospital scanning?	unit dose for		Is this product covered u	nder the				& V23, 1 mg - H & V24			/ial Powder Sgl			Each	ich package t	type r
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No						/ial Powder Multi			Inner/Cartor	n/Pack	
											Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS												
									PHARMACY ORDER / BILL UNIT							
				horized Generic *If Authorized Generic, other section fields are not applicable						ARMACY ORDER						
I. Orange Book Rating:	AB	Chantin				section fields are not applicable			Rec. sell unit	t to custome	er?	1	Rx billing unit to pharmacy:			
II. Generic Equivalent to What Brand?:  Chantix						(Write-in, e.g. 1 Vial)				Each Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMA				RMATION			(*************************************				Milliliter					
			,	•												
Does supplier meet DSCSA definit	ition of manufactu	rer?	Yes		GLN:	0331722498975					ITEN	I AND PACKING II	NFORMATIO	N		
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:						Weight Lbs.		ons (US msn	•	Volume	Saleable #
Other exemption - Write in:			No		W	talastas t						Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	avelusive distrib	utor?	No Yes	-	If yes, was or direct from m	iginal product pur	chased		Item/Each:		0.27	7.4	1.3	4	38.48	1
Has FDA granted waiver/exception			No No	+		or : ce manufacturer fo	or repact	kaged product	Box/Carton/E	Bundle/						
If yes, attach documentation from								3 p	Inner Pack:							
									Case:		13.6	15.25	11.5	12.5	2,192.19	48
		G.	TIN AND HIBCC PRODUCT IF	IFORMATION								10.20		.2.0	2,102.10	
Saleable Unit of Measure	,	and the contract	LUDOO		OTU			Hallace III a OTINI 44	Pallet:							
X Item/Each		Saleable Quantity	HIBCC			N-14 31722690317		Unit of Use GTIN-14 00331722690317								
Box/Carton/Bundle/Inner Pack					00001122000011	COST INFORMATION				WHOLESALER USE ONLY:						
X Case		48			203	31722690311										
Pallet									Regular Cos	t			Vendor #:			
									Invoice Cost	(WAC) (\$)		\$95.00	Whsl. Code			
										E-	/31/2024		Fineline Co	de:		
	-						_		As of date:	Ľ	131/2024		-			
ľ			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza	rd letter, PACKAGE	INSER	RT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and	BARCODE.					
*Please provide any additional info	ormation on page	2		0 (01	, oouza			nated Dron Shin Only		Signature						



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

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic?  No	SDS Hazard Classification						
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?  No  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 e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
Is this product regulated for shipment by IATA?	LFA Hazaruous waste code.						
(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?  No 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#	Registry: No						
GF#	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product  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	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  Is product returnable for credit:  Yes						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	product in certain states?  No If so, which states? Other requirements? Comments?						
Comments:							
	OUS NOTES and/or Image of Product Barcode:						
**NOTE -Combination Starter Package - 0.5 mg - Pink, debossed with 'H' on one side and 'V23' on the o	her side. 1 mg - Yellow, debossed with 'H' on one side and 'V24' on the other side.						



## **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?