



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

Version 2021 Introduction Type: 0000 Final Version Date:

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: Camber Pharmaceuticals, Inc. **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214571
Medical Device Class, if applicable: _____
DUNS: 11-856-3719
Proprietary Name (If Applicable) and Established Name: Varenicline Tablets 0.5 mg & 1 mg
Selling Unit NDC: 31722-690-31 **Unit of Use NDC:** 31722-690-31 **UPC:** 331722690317
UDI _____ **CVX Code:** _____ **MX Code:** _____
Description: Varenicline Tablets 0.5 mg & 1 mg
Active Ingredient(s): Varenicline tartrate
URL for Additional Product Information: www.camberpharma.com
Address: 800 Centennial Ave, Suite 1 **Address 2:** _____
City: Piscataway **State:** NJ **Zip:** 08854
Key Contact: Customer Service **Email:** customerservice@camberpharma.com
Phone Number: 1-866-827-3647 **Fax:** 732-562-8788
Product Therapeutic Classification: Nicotinic receptor partial agonist

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range
Other Temperature Range Requirement
Notes _____
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?
b. Contact for temperature excursion questions:
Name: Soma Raju
Number: 732-529-0423
Group E-mail: somaraju@heterousa.com
c. Special regulations for product in any states?
 Special returns requirements for this product?
d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light?
e. Shelf life: Months
 Initial shelf life at launch (if different): _____ Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? <input type="text" value="No"/>	Is the Product... Direct-Ship Only <input type="text"/>	Size: 53 ct	
if yes, enter class # a product kit? <input type="text" value="No"/>	Is the Product... Unit of Use <input type="text"/>	Strength: 0.5 mg & 1 mg	
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	Orphan Drug Status <input type="text"/>	Dosage Form: Film coated tablets	
co-licensed? <input type="text" value="No"/>	FDA Approval Status <input type="text"/>	Product Shape: Capsular, biconvex	
latex-free? <input type="text" value="Yes"/>	Allergens Present <input type="text" value="Alcohol"/>	Product Color: **See Note** 0.5 mg - Pink, 1 mg - Yellow	
preservative-free? <input type="text" value="Yes"/>	Country of Origin <input type="text" value="India"/>	Product Imprint: **See Note** 0.5 mg - 'H' & 'V23', 1 mg - 'H' & 'V24'	
correctional institution block? <input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>		
opioid? <input type="text" value="No"/>			
Cannabinoid? <input type="text" value="No"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>			
If Unit Dose, indicate NDC here: <input type="text"/>			

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Carton of 53 Tablets
<input type="checkbox"/> x Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="48"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/Carton/Pack
<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In _____	

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
Is product exempt from DSCSA?
GLN: 0331722498975
GCP: _____
If yes, select exemption: _____
Other exemption - Write in: _____
Is product repackaged?
Is product sold by manufacturer's exclusive distributor?
Has FDA granted waiver/exception/exemption for product?
If yes, attach documentation from FDA. _____
If yes, was original product purchased direct from mfr?
Provide source manufacturer for repackaged product _____

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.27	7.4	1.3	4	38.48	1
Box/Carton/Bundle/Inner Pack:						
Case:	13.6	15.25	11.5	12.5	2,192.19	48
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722690317	00331722690317
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		20331722690311	
<input type="checkbox"/> Pallet				

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost _____
Invoice Cost (WAC) (\$)
As of date:
Vendor #: _____
Whsl. Code #: _____
Fineline Code: _____



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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
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a CA Prop 65 reproductive toxicant? No
 - Does the product label bear a CA Prop 65 warning? No

- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

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

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

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)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No Yes
- Controlled Substance Code
- Controlled by State(s)? No Yes
- Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- Restricted to retail pharmacy only: No Yes
- Restricted to hospital, clinics, and physician offices only: No Yes
- Restricted from US territories? (explain in comments) No Yes

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

Is the product a NIOSH hazardous drug? If yes, indicate which: No

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes

If Yes, is it managed with a pharmacy registry? Website URL:

Med Guide Required No Yes

Limited Distribution Requirement No Yes

Comments / Details: (For example, iPledge program?)

REMS: REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively: No Yes

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

Comments

Registry: No Yes

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: Yes No

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No Yes

If so, which states? Other requirements? Comments?

MISCELLANEOUS 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 other side. 1 mg - Yellow, debossed with 'H' on one side and 'V24' on the other side.

