

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

Version 2021					Introduction 1	Type: Pos	st Launch Change		x Final Version			Date:	6/23/	/2024
		PRODUCT INFORM	ATION						SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*	*	
Company Name: Camber Pharmaceuticals, Inc. Application:					tion:	ANDA	a. Temperature	- Indicate the USP tempe	rature range for t	his product.				
Application Number for NDA/AN			203034						Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat														
DUNS:	11-856-3719							· (	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		Donepezil Hydrochloride Tablets							(write in)					
Selling Unit NDC:	31722-738-30	Unit of Use NDC	317	22-738-30	UPC:	33172273830	9	1	Notes					
UDI		CVX Code:			MVX Code:									
Description:	Donepezil Hydrochloride Ta	blets, USP 10 mg							Is this product to be shipped				No	]
Is this product to be shipped to customers on dry ice? No														
Active Ingredient(s): Donepezil hydrochloride, USP b. Contact for temperature excursion questions:														
URL for Additional Product Information: www.camberpharma.com								Name: Soma Raju						
Address:	800 Centennial Ave, Suite 1				Address 2:				Number:		732-529-042	23		
City:	Piscataway			State:	NJ	Zip: 0885	4		Group E-mail:			neterousa.cor	n	
Key Contact:	Customer Service			Email:	customerservice				•				_	
Phone Number:	1-866-827-3647			Fax:	732-562-8788			c. Special regu	lations for product in any	states?			No	]
Product Therapeutic Classification	n: Acetylch	olinesterase inhibitor						5	Special returns requirement	s for this product?			No	
														-
	ADDITIONAL PR	ODUCT INFORMATION			PRODUCT	DESCRIPTION	INFORMATION	d. Store produc	ct (unit of sale) upright?				No	
The product is?		Is the Product	Direct-Ship Only		1				Protect product (unit of sa	le) from light?			No	
a legend device?	No	Is the Product	Unit of Use		Size:	30 ct		e. Shelf life:					24	Months
if yes, enter class #		Orphan Drug Status				10.		'	Initial shelf life at launch (	if different):				Months
a product kit?	No	FDA Approval Status			Strength:	10 mg				ORDER INFORM				
if yes, list NDCs of component parts		PDA Approvar Status				Film co	bated tablet			ORDER IN ORI	ATION			
reverse numbered?	No				Dosage Form	n:		L L	Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present							x Bottle		1 Bottle of 3			
latex-free?	Yes		actose		Product Sha	Round	, biconvex	_	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?	Yes	-	actose		Froduct Sha	ipe.			Ampule					
correctional institution block?	No				Product Col	or: Yellow			Glass		Minimum or	rder quantity	?	Yes
opioid?	No		1				al suide 111 an ann a side	_	Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	No	Country of Origin	India		Product Imp		d with 'I' on one side on the other side	-	Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ch package i	h/no?
hospital scanning?	Init dose for	Is this product covered	under the					-	Vial Equid Multi Vial Powder Sgl			Each	ch package	type :
If Unit Dose, indicate NDC here:		Trade Agreements Act						-	Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
-		FOR GENERIC DRUG P	RODUCTS									4		
											_			
				Aut	thorized Generic		Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					section fields	are not applicable	Rec. sell unit to	o customer?	_	Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	nd?: Aricept											Each		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g. 1	Vial)			Gram Milliliter			
	DK	US SUFFET CHAIN SECORTT ACT	(DSCSA) INFORMAT	TION								winniter		
Does supplier meet DSCSA definit	tion of manufacturer?	Yes	GLM	N:	0331722498975				ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?		No												
If yes, select exemption:			GCI	P:						Dimensi	ons (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No			iginal product pur	chased		Item/Each:	0.06	1.5	1.5	3	6.75	1
Is product sold by manufacturer's		Yes		ect from m									0.10	
Has FDA granted waiver/exception If yes, attach documentation from		No	Pro	ovide sourc	e manufacturer fo	or repackaged	product	Box/Carton/But Inner Pack:	ndle/					
If yes, attach documentation from	m FDA.							Case:						
		GTIN AND HIBCC PRODUCT	INFORMATION					ouse.	3.75	12.5	9.5	4.25	504.69	48
								Pallet:						
Saleable Unit of Measure	Saleable Q	uantity HIBCC		GTIN			of Use GTIN-14							
X Item/Each	1			0033	31722738309	0033	1722738309							
Box/Carton/Bundle/Inner Pack						-			COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case Pallet	48			2033	31722738303	-		Benular Cost			Vandard			
Pallet						-		Regular Cost Invoice Cost (W		CA 40	Vendor #: Whsl. Code	#-		
								invoice cost (V		φ4.40	Fineline Co			
								As of date:	9/15/2015					
											1			
<u> </u>											<u> </u>			
		Attach copy of SAFETY I	DATA SHEET (SDS) or	r non hazar										
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:														

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

	nated 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? Does the product label bear a CA Prop 65 warning? C. Contact Hazard? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	x       Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Image: Contact Hazard					
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	Is the product a NIOSH hazardous drug? If yes, indicate which: Hazardous Waste Identification					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? No (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? Is the product restricted for air shipment? If so, indicate restriction: No	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         If Yes, is it managed with a pharmacy registry?       No         Website URL:       No         Med Guide Required       No					
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 Provision (listed in Column 7 of 49 CFR 172.101);	Limited Distribution Requirement Comments / Details: (For example, iPledge program?)  REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: Comments					
SP#	Registry: No					
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name:     Phone:       Comments					
Controlled Substance?         No         Controlled Substance Code           Controlled by State(s)?         No         Listed Chemical (List I or II)         No	RETURN INSTRUCTIONS					
Controlled by State(s)?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:       If yes, indicate which:         Schedule No.       Is it a scheduled listed chemical product?:       No         CLASS OF TRADE RESTRICTION:         No restriction:       Select YES if sold to retail pharmacy, hospitals, clinics and physician offices       Yes	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:       No         Restricted to hospital, clinics, and physician offices only:       No         Restricted from US territories? (explain in comments)       No	Special regulations or returns requirements for this product in certain states?       No         If so, which states? Other requirements? Comments?					
Comments:						
MISCELLA	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 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?