

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

Version 2021					Introduction	Type: Po	st Launch Change		x Final Version			Date:	6/23/	2024
		PRODUCT INFORM	ATION						SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*	m	
Company Name: Camber Pharmaceuticals, Inc. Applicat					tion:	ANDA	a. Temperature	- Indicate the USP temp	erature 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	Requirement				
Proprietary Name (If Applicable) a		Donepezil Hydrochloride Tablets,							(write in)					
Selling Unit NDC:	31722-738-90	Unit of Use NDC	3172	22-738-90	UPC:	3317227389	03	1	Notes					
UDI		CVX Code:			MVX Code:									
Description:	Donepezil Hydrochloride Tab	olets, USP 10 mg							Is this product to be shippe				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 Inform	nation: www.cam	berpharma.com							Name:	estions.	Soma Raju			
Address:	800 Centennial Ave, Suite 1				Address 2:				Number:		732-529-042	23		
City:	Piscataway			State:	NJ	Zip: 0885	54		Group E-mail:		somaraju@h	neterousa.cor	<u>n</u>	
Key Contact:	Customer Service			Email:	customerservice	@camberpharr	na.com							
Phone Number:	1-866-827-3647			Fax:	732-562-8788				lations for product in any				No	
Product Therapeutic Classification	n: Acetylcho	linesterase inhibitor							Special returns requirement	is for this product?			No	
		DOUCT INFORMATION			PRODUCT	DESCRIPTION		d 644	at (unit of col-)!-! -?				N-	
	ADDITIONAL PRO				PRODUCT	DESCRIPTION	INFORMATION	-	ct (unit of sale) upright?				No	
The product is?		Is the Product	Direct-Ship Only						Protect product (unit of sa	ale) from light?			No	
a legend device?	No	Is the Product	Unit of Use		Size:	90 ct		e. Shelf life:	Initial chalf life at laws - 1. (	if different)			24	Months
if yes, enter class # a product kit?	No	Orphan Drug Status				10 mc	1		Initial shelf life at launch (	n unterent):				Months
if yes, list NDCs of		FDA Approval Status			Strength:	10 mg	,			ORDER INFORM	IATION			
component parts					Dosage For	Film c	oated tablet							
reverse numbered?	No				Dosage For	m:			Unit of Sale			NDC selling	unit?	
co-licensed?	No	Allergens Present							x Bottle		1 Bottle of 9			
latex-free?	Yes	Li	actose		Product Sha	ape: Round	d, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	) Vials)	
preservative-free?	Yes					-		-	Ampule				•	Mar
correctional institution block?	No				Product Col	or: Yellov	v	-	Glass Tube		Minimum or	rder quantity	?	Yes
Cannabinoid?	No	Country of Origin	India			Deboss	ed with 'I' on one side	-	Vial Liquid Sql					
If Unit Dose, is item bar coded to u					Product Imp		on the other side		Vial Liquid Multi		If Yes, how	many of whi	ch package t	ype?
hospital scanning?		Is this product covered	under the						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act	(TAA)? No						Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
		FOR GENERIC DRUG P	RODUCTS											
				A.,+	horized Generic	*If Authorizor	d Generic, other	PHARMACY ORDER / BILL UNIT						
	40		_	Au	nonzeu Generic		are not applicable	Dee cell unit to						
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Aricept			section fields are not applicable Rec. sell unit to customer?			1	Rx billing unit to pharmacy: Each							
II. Generic Equivalent to what Bra	Апсерс							(Write-in, e.g. 1	Vial)			Gram		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							,			Milliliter				
												4		
Does supplier meet DSCSA defini	tion of manufacturer?	Yes	GLN	N:	0331722498975				ITEN	I AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?		No												
If yes, select exemption:			GCF	P:					Weight Lbs.		ons (US msm	-	Volume	Saleable #
Other exemption - Write in:		No						14 a m / T		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	exelucive distributor?	Yes		es, was ori ect from m	iginal product pur	chased		Item/Each:	0.12	1.5	1.5	3.25	7.31	1
Has FDA granted waiver/exception		No			e manufacturer fo	or repackaged	product	Box/Carton/Bu	ndle/					
If yes, attach documentation from				nuo ooure		opuonagou	product	Inner Pack:						
								Case:	6.15	12.5	9.5	4.25	504.69	48
		GTIN AND HIBCC PRODUCT	INFORMATION						0.10	12.5	5.0	4.20	004.00	+0
Only the Unit of Management								Pallet:						
Saleable Unit of Measure	Saleable Qu	antity HIBCC		GTI			of Use GTIN-14	L						
X Item/Each Box/Carton/Bundle/Inner Pack	1 00331722738903 00331722738903					51122130903		WHOLESALER USE ONLY:						
X Case	48			2033	31722738907				COST INFORMATION					
Pallet						_		Regular Cost			Vendor #:			
								Invoice Cost (V	VAC) (\$)	\$13.20	Whsl. Code			
											Fineline Co			
						-		As of date:	9/15/2015					
<u> </u>		Attach copy of SAFETY D		- non +	d lattar BACKACS						ļ			
*Please provide any additional inf	ormation on page 2	Allach Copy of SAFETY L	ATA SHEET (SUS) OF	non nazar	See new p. 3 for				SING and BARCODE.					
r lease provide any additional info	ormation on page 2.				See new p. 5 for	Designated L	nop onip Oniy.		orginature.					

## **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?