

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014 Post Launch Change Final Version Date: 4/12/2017															
			PRODUCT INFORMA	ATION						SPECIAL HANDL	ING AND STO	RAGE REQ	JIREMENTS*	•	
Company Name:	Camber Pharmaceuti	rals				App	lication:	ANDA	a Temperature – Indic	ate the USP temper	aturo ranno f	or this prod	ıct		
	DA/ANDA/BLA (drug); PMA/510(k)(med device):			203034	203034			a. Temperature – Indicate the USP temperature range for this product.  Temperature Range  Controlled Room – between 20 and 25 C (68° – 77°							
DUNS:	82-667-4775		<u>,                                      </u>						-	emperature Range Re					
Proprietary Name (If Applicat		Name: Donopoz	il Hydrochloride 5MG 90CT							rite in)	quirement				1
Selling Unit NDC:	31722-737-90	varrie. Donepez	Individual Unit NDC:		22-737-90	UPC:	33172273790	06	- (w	inte iii)					1
UDI	NA NA		CVX Code:	[011.	22 707 00	MVX Code:	NA	-	Is this pr	oduct to be shipped to	customers o	n ice?		No	
Description:	White to off white re-	nd tablete ambassed with	'24' on upper punch and 'I'	on lower numb			<u> </u>		<b>= 1</b>	oduct to be shipped to				No	-
Description.	write to oii-write loc	nu tablets embosseu witi	1 24 On upper punch and 1	on lower punch					is this pi	oduct to be shipped to	J Customers C	ii diy ice :		INU	=
Active Ingredient(s):		Donepezil Hydrochloride	1						b. Contact for tempera	ature excursion que	stions:				
									Name:	·		Soma Raju			
URL for Additional Product Information: www.camberpharma.com								Number:			732-529-0423				
Address:	1031 Centennial Avenue				Address 2:			Group E	-mail:		somaraju@h	eterousa.cor	n		
City:	Piscataway				State: NJ Zip: 08854 Email: customerservice@camberpharma.com			4							
Key Contact: Phone Number:	Customer Service 732-529-0430				Fax: 732-562-8788			c. Special regulations			+2		No No	-	
					10x. 132-302-0700			Special returns requirements for this product? NoNo					-		
Troduct Therapeutic Glassin	Product Therapeutic Classification:  d. Store product (unit of sale) upright?  No														
ADDITIONA	AL PRODUCT INFORM	ATION	1		PR	ODUCT DESCRIF	TION INFORM	IATION		product (unit of sale	) from light?			No	-
Is the Product					PRODUCT DESCRIPTION IN ORMATION				11				Months		
a legend device?		No											Months		
reverse numbered?		No		Size	<b>)</b> :	90				(!! (			ļ		
co-licensed?		No		C4	ength:	5 mg				(	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only		Sile	angun.	5 mg									
Is the Product		Unit of Use		Dos	age Form:	Oral Solid	tablet		Unit of S				NDC selling	unit?	
					•					Bottle		I box of 12 b		0.15-1-1	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?							x	Box/Carton Ampule		(vvrite-in, e.	g. 1 Box of 1	u viais)	
If Unit Dose NDC, indicate NI	DC here:			Pro	duct Shape:	round				Glass		Minimum o	der quantity	?	Yes
ii onic bood nebo, indicato ne	.50 11010.			B		1.2				Tube			uoi quuinny		
Country of Origin		India		Pro	duct Color:	white				Vial Liquid Sgl					
Is this product covered under the Trade Agreements Act (TAA)? Product Imprint: 24/Ti							Vial Liquid Multi If Yes, how many of which package type?					type?			
		No No								Vial Powder Sql		40	Each	/D 1	
									J	Vial Power Multi Other: Write In		12	Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PR	RODUCTS						Other, write in			Case		
											_				
					Authoriz	ed Generic	*If Authorized	Generic, other section		PHAR	MACY ORDE	R / BILL UNI	T		
I. Orange Book Rating: AB			fields are not applicable			Rec. sell unit to custo	mer?		Rx billing u	nit to pharma	acy:				
II. Generic Equivalent to What Brand?: Aricept			•							Each					
-							(Write-in, e.g. 1 Vial)		_		Gram				
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFORM	ATION								Milliliter		
Dana summilian mant DSCSA			Yes	GLN:	Г					ITEM A	ND PACKING	INFORMATI	ON		
Does supplier meet DSCSA of Is product exempt from DSC			No	GLN:	L					ITEMA	ND FACKING	INFORMATI	ON		
If yes, select exemption:				•							Dimer	sions (US m	smts.)	Volume	=.
Other exemption - Write in:	:									Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No	If Yes, v	vas original p	roduct purchase	d direct		Item:	0.1		2.5	1.5		
Is product sold by manufact			No	from mi				<u> </u>		5.1		2.0	0		
Has FDA granted waiver/exc	ception/exemption for	product?	No	If yes, a	ttach docum	entation from FI	PA.		Box/Carton/Bundle/	1	6.625	3.25	4.875	0.061	12
			GTIN PRODUCT INFOR	MATION					Inner Pack: Case:						
			GTIN FRODUCT INI OR	Saleable					Case.	11.65	14.75	8.5	8.375	0.608	96
			Level	Unit			Quantity	GTIN-14	Pallet:						0500
Serialized?	Yes	х	Item	х	2D	Linear		00331722737906							2592
If not, when?		х	Box/Carton/Bundle/Inner Pack	х	2D	Linear	12	10331722737903	UPC:	Case:		•			
Items aggregated?	Yes	х	Case	х		Linear	96	30331722737907		Carton:					
			Pallet	$oxed{oxed}$	2D	Linear			-000	INFORMATION		_	WHO! FOAT	ER USE ONI	V
		$\vdash$		<b>├</b> ──	2D 2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ON	-11
		<del></del>		├──	2D 2D	Linear			Regular Cost			Vendor #:	j		
					2D Linear 2D Linear				Invoice Cost (WAC) (\$) \$13.20						
			,						Federal Excise Tax Pe		Ţ.J.20	Fineline Co			
									As of date:						
			Attach copy of SAFETY D	ATA SHEET (SDS)					ODUCT PACKAGING and BA						
*Please provide any addition	nal information on pag	je 2.			5	See new p. 3 for I	Designated Dr	rop Ship Only.	Signatu	re:					



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cvtotoxic?  No	SDS Hazard Classification							
	SDS HAZAFU CIASSILICATION							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive							
Is the product a CA Prop 65 reproductive toxicant?	Inorganic							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
	_							
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions?								
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?							
e. Does the product contain DEHP?	If yes, indicate which:							
· ———								
Is this product regulated for shipment by DOT or IATA?  No								
(if yes, answer a-e below and provide SDS)								
a. UN/Identification Number								
b. Proper Shipping Name	Hazardous Waste Identification							
c. DOT Hazard Class	EPA Hazardous Waste Code: N/A							
d. Packing Group								
e. Inhalation Hazard?								
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS							
Passenger	Is there a REMS on this product?							
	·							
Cargo	If Yes, is it managed with a pharmacy registry?							
Passenger & Cargo	Website URL:							
Is this a reportable quantity? No								
RQ Threshold:	Comments / Details: (For example, iPledge program?)							
Is this a marine pollutant? No	The state of the s							
Is this product shipped utilizing an authorized DOT exception or Special Permit?								
No (if yes, identify method below)	REMS:							
Limited Quantity	REMS Program Manager Name: Phone:							
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No							
Small Quantity (49 CFR 173.4)	Wholesale distributor support:  No  No							
Special Permit; DOT-SP	Provider Name:							
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned  DEA #: No							
SP#	by Supplier: PCPDP #: No							
	NPI #: No							
ADD'L STORAGE INFORMATION								
Is the Product	Comments							
Controlled Substance? No								
Controlled by State(s)?	Registry: No							
ARCOS Reportable? No	Registry Program Contact Name: Phone:							
Schedule No. (inc. N for non-narcotic)	Comments							
Controlled Substance Code								
Listed Chemical (List I or II)	RETURN INSTRUCTIONS							
If yes, indicate which:								
Is it a scheduled listed chemical product?:	Contact tel. # if product received damaged: 732-529-0430							
CLASS OF TRADE RESTRICTION:								
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:  Yes							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy: contact - customerservice@camberpharma.com							
Restricted to retail pharmacy only:  Yes	Special regulations or returns requirements for this product in certain states?							
Restricted to hospital, clinics, and physician offices only:  No	If so, which states? Other requirements? Comments?							
Restricted from US territories? (explain in comments)  No								
Comments:								
MISCELLAN	NEOUS NOTES and/or Image of Product Barcode:							



## **Standard Pharmaceutical Product Information (Page 3)**

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  Yes  No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern					
c. Fax  d. Phone only  No Phone No.:	Shipping lead time of PO: 24/48 Hours Days					
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No					
Minimum Order Quantity: case pack	Ships for second day receipt:  No					
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt:  Yes					
Contracted 3PL company / contact #: Name: Phone:						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order: No No	Overnight receipt available: Yes					
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern					
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:					
Comments:	x Tuesday x Wednesday Thursday x Friday					
	Priority Overnight receipt available: Yes					
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No					
Restricted to retail pharmacy only:  Yes	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only:  No	Order receipt method:  No Phone #:					
Restricted from US territories? (explain in comments)  No	Fax: Yes Fax #: 732-562-8788					
Comments:	EDI: Yes					
	Overnight Fees apply:  Other fees apply:  No					
Other Data Information Demoired to Decree DO						
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date:  Physician Name:	Contact # if product is received damaged:  Is product returnable for credit:  Yes					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #	Special regulations or returns requirements for this product in certain states?  Yes					
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:	·					
Miscellaneous Notes:						
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					
	Is product order for restocking purposes?					