

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

Version 2021							Introduction 1	Туре:	Post Launch Change		Final Version			Date:	6/23	/2024	
				PRODUCT INFORMA	TION						SPECIAL HAN	NDLING AND STO	RAGE REQUII	REMENTS*	*		
Company Name:	Camber Pharmace	euticals, Inc.					Applica	ation:	ANDA	a. Temperature – I	ndicate the USP temp	erature range for t	this product.				
Application Number for NDA/AN	Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203034								perature Range	Controlled Room		and 25 C (68	° – 77° F)				
Medical Device Class, if applicat																	
DUNS:	11-856-3719									Oth	er Temperature Range	Requirement					
Proprietary Name (If Applicable) a		me: D	onepezil	Hydrochloride Tablets,							(write in)						
Selling Unit NDC:	31722-738-05			Unit of Use NDC			UPC:	3317227	38057	Note	S						
UDI				CVX Code:			MVX Code:										
Description: Donepezil Hydrochloride Tablets, USP 10 mg									is 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 Information: www.camberpharma.com									Name: Soma Raju								
Address:	800 Centennial Ave, Suite 1				Address 2:			Nur	732-529-042	3							
City:					State:	NJ				Group E-mail:				somaraju@heterousa.com			
Key Contact:	Customer Service					Email:	customerservice	customerservice@camberpharma.com			•				_		
Phone Number:	1-866-827-3647	6-827-3647 Fax			Fax:	732-562-8788			c. Special regulati	ons for product in any	/ states?			No]		
Product Therapeutic Classification	ation: Acetylcholinesterase inhibitor Special returns I							cial returns requiremen	ts for this product?			No					
	ADDITIO	ONAL PRODUC	T INFOR	MATION			PRODUCT	DESCRIPT	TION INFORMATION	d. Store product (u	nit of sale) upright?				No		
The product is?			1	s the Product	Direct-Ship C	Only				Pro	ect product (unit of s	ale) from light?			No]	
a legend device?		No		s the Product	Neither		Size:	50	00 ct	e. Shelf life:					24	Months	
if yes, enter class #				Orphan Drug Status			0120.			Initi	al shelf life at launch	(if different):				Months	
a product kit?		No					Strength:	10	0 mg								
if yes, list NDCs of				FDA Approval Status			•	-	Nex exercised to block			ORDER INFORI	MATION				
component parts reverse numbered?		Ne					Dosage Form	m:	ilm coated tablet	Unit	of Sale		What is the	NDC selling	unit?		
co-licensed?		No No		Allergens Present							Bottle		1 Bottle of 5		unit:		
latex-free?		Yes	i i	-				R	ound, biconvex		Box/Carton			g. 1 Box of 1	() Vials)		
preservative-free?		Yes		La	ctose		Product Sha	ape:			Ampule		(g			
correctional institution block?		No					Product Col	Ye	ellow		Glass		Minimum o	der quantity	?	Yes	
opioid?		No					Product Col				Tube						
Cannabinoid?		No	(Country of Origin	India		Product Imp		ebossed with 'I' on one side nd '21' on the other side		Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	init dose for							an	Id 21 on the other side		Vial Liquid Multi		If Yes, how		ch package	type?	
hospital scanning?				s this product covered							Vial Powder Sgl		12	Each			
If Unit Dose, indicate NDC here:				Trade Agreements Act	IAA)?	No					Vial Powder Multi Other: Write In	I		Inner/Carton	/Pack		
			FO	R GENERIC DRUG PF	ODUCTO						Other: white in			Case			
			FC	JR GENERIC DRUG PI	CODUCIS												
						Au	uthorized Generic	*If Autho	rized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB								ields are not applicable	Rec. sell unit to cu				nit to phorm	2014		
I. Generic Equivalent to What Brand?: Aricept							Rec. sell unit to customer? Rx billing unit to pharmacy:				acy.						
												Gram					
		DRUG SI	JPPLY C	HAIN SECURITY ACT	(DSCSA) INFOR	RMATION				(,	,			Milliliter			
							-						1				
Does supplier meet DSCSA definit	tion of manufacture	er?		Yes		GLN:	0331722498975				ITEI	M AND PACKING I	NFORMATIO	١			
Is product exempt from DSCSA?	l			No													
If yes, select exemption:						GCP:					Weight Lbs.		ions (US msn	-	Volume	Saleable #	
Other exemption - Write in:	ļ			N1-								Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?				No	_		riginal product pur	rchased		Item/Each:	0.4	2.5	2.5	4	25	1	
Is product sold by manufacturer's Has FDA granted waiver/exception				Yes	_	direct from n	ntr? ce manufacturer fo		and an educat	Box/Carton/Bundle	.1						
If yes, attach documentation from				NO		FIOVICE SOUL		оптераска	iged product	Inner Pack:							
in yes, attach documentation nor	IT DA.									Case:							
			GTIN A	ND HIBCC PRODUCT	NFORMATION						5.4	10.5	8	5.5	462	12	
										Pallet:							
Saleable Unit of Measure	Sa	aleable Quantity	γ I	HIBCC			IN-14		Unit of Use GTIN-14								
X Item/Each	[1				003	31722738057	_									
Box/Carton/Bundle/Inner Pack								_			COST INFORMATION			WHOLESALI	ER USE ONL	Y:	
X Case	,	12				203	31722738051	_									
Pallet			_					_		Regular Cost) (†)		Vendor #:				
	-		-					-		Invoice Cost (WAC) (\$)	\$73.33	Whsl. Code Fineline Co				
	-		-					-		As of date:	10/28/2016		rineine Co	ue:			
			-					-		As of udie.	10,20,2010		-				
[•			Att	ach copy of SAFETY D	ATA SHEET (SD	S) or non haza	ard letter, PACKAGE	E INSERT.	LABEL AND PHOTO OF F	PRODUCT PACKAGING	and BARCODE.		•				
*Please provide any additional infe	ormation on page 2	2.			,				ed Drop Ship Only.		ature:						
	. •						-	-									

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	SDS Hazard Classification x Organic 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?