

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

Version 2021						Introduction 1	Type: P	ost Launch Change	X	Final Version			Date:	6/23/	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOP	RAGE REQUIR	EMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Applica	ition:	ANDA	a. Temperature – Indic	ate the USP tempe	erature range for t	his product.			
Application Number for NDA/AN	DA/BLA (drug); PN	/A/510(k)(med de	evice):	203	3034					ature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat															
DUNS:	11-856-3719								Other Te	emperature Range I	Requirement				
Proprietary Name (If Applicable) a		me: Do	nepezil Hydrochloride Tablets,	JSP 5 mg						rite in)					
Selling Unit NDC:	31722-737-30		Unit of Use NDC:		31722-737-30		3317227373	302	Notes						
UDI			CVX Code:			MVX Code:									
Description:	Donepezil Hydrock	hloride Tablets, U	ISP 5 mg							roduct 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 Inform	nation:	www.camberpha	arma com						b. Contact for tempera Name:	iture excursion qu	estions:	Soma Raju			
Address:	800 Centennial Av					Address 2:			Number	•		732-529-042	3		
City:	Piscataway State:				NJ Zip: 08854			Group E-mail:			eterousa.com	1			
Key Contact:	Customer Service				customerservice		<u>rma.com</u>								
Phone Number:	1-866-827-3647	-866-827-3647 Fax:			732-562-8788			c. Special regulations	for product in any	states?			No]	
Product Therapeutic Classification	n:	Acetylcholineste	erase inhibitor						Special	returns requirement	ts for this product?			No	
					_										4
	ADDITIC	ONAL PRODUCT	INFORMATION			PRODUCT	DESCRIPTIO	N INFORMATION	d. Store product (unit	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only	1			Protect	product (unit of sa	ale) 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						Initial sl	helf life at launch (if different):				Months
a product kit?		No				Strength:	5 mg								
if yes, list NDCs of component parts			FDA Approval Status				Film	coated tablet			ORDER INFORM	ATION			
reverse numbered?		No				Dosage Form	m: ["""	coaled lablel	Unit of S	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x	Bottle		1 Bottle of 30			
latex-free?		Yes	_	tose		Barrier Ola	Rour	nd, biconvex		Box/Carton			g. 1 Box of 10	Vials)	
preservative-free?		Yes	La	ctose		Product Sha	ape:			Ampule					
correctional institution block?		No	1			Product Col	White	e		Glass		Minimum or	der quantity	?	Yes
opioid?		No				i iouuci ooi				Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp		sed with 'I' on one side 4' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u hospital scanning?	init dose for		Is this product covered u				010 2			Vial Liquid Multi Vial Powder Sgl		If Yes, how 48	nany of white Each	ch package t	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (No					Vial Powder Sgi			Each Inner/Carton/	Pack	
in offit bose, indicate type here.			Induc Agreements Act (NO					Other: Write In			Case	I dok	
			FOR GENERIC DRUG PR	ODUCTS											
									-						
					Au	thorized Generic		ed Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section field	ls are not applicable	Rec. sell unit to custor	mer?		Rx billing u	nit to pharma	cy:	
II. Generic Equivalent to What Brand?: Aricept											Each				
							(Write-in, e.g. 1 Vial)		_		Gram				
		DRUG SUI	PPLY CHAIN SECURITY ACT	DSCSA) INFOR	RMATION								Milliliter		
Doos supplier most DSCSA definit	tion of monufactur		Yes	_	GLN:	0331722498975				ITEN	I AND PACKING I				
Does supplier meet DSCSA definit Is product exempt from DSCSA?	non or manuractur		No	-	GLN.	0331722496975					A AND T ACKING I				
		I			GCP				1		Dimonsi	ions (US msm	te)	Values	Calcal I. #
If yes, select exemption: Other exemption - Write in:					GCP:					Weight Lbs.	Dimensi	Width	Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes was or	iginal product pur	chased		Item/Each:		1		_		
Is product sold by manufacturer's	exclusive distribu	itor?	Yes	-	direct from m		chused		item/Eden.	0.05	1.5	1.5	2.5	5.63	1
Has FDA granted waiver/exception			No	-		ce manufacturer fo	or repackage	d product	Box/Carton/Bundle/						
If yes, attach documentation from	m FDA.								Inner Pack:						
									Case:	3	12.5	9.5	4	475.00	48
			GTIN AND HIBCC PRODUCT I	NFORMATION						-					
Saleable Unit of Measure	-								Pallet:						
X Item/Each	S	aleable Quantity	HIBCC			N-14		t of Use GTIN-14 331722737302							
Box/Carton/Bundle/Inner Pack							01122101002	COS	T INFORMATION			WHOLESALE	R USE ONL	Y:	
X Case		48			203	31722737306									
Pallet							-		Regular Cost			Vendor #:			
									Invoice Cost (WAC) (\$)	\$4.40	Whsl. Code			
												Fineline Co	le:		
	_						_		As of date:	9/15/2015		ļ			
												1			
μ									Ц			ļ			
			Attach copy of SAFETY D/	ATA SHEET (SD	S) or non haza										
*Please provide any additional infe	ormation on page	2.				See new p. 3 for	r Designated	Drop Ship Only.	Signatu	re:					

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:						



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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?