

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

Version 2024							Introduction	Type:	New Item		x Final Version			Date:	12/19	9/2024
				PRODUCT INFORMAT	TION						SPECIAL H	ANDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN			204389				NDA 505(b) Type		NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical											· -					
DUNS:	11-856-3719	_								·	Other Temperature Ran	ge Requirement				
Proprietary Name (If Applicable) a		lame:	Memantir	ne Hydrochloride Tablets,	USP 10 mg						(write in)					
Selling Unit NDC:	31722-808-60			Unit of Use NDC:		31722-808-60		3317228	308606		Notes					
UDI				CVX Code:			MVX Code:			Į.						
Description:	Memantine Hydro	ochloride Table	ets, USP 1	0 mg							Is this product to be ship	ped to customers on i	ce?		No	1
											Is this product to be ship	ped to customers on o	dry ice?		No	
Active Ingredient(s): Memantine hydrochloride, USP																
URL for Additional Product Information: www.camberpharma.com									b. Contact for temperature excursion questions:							
URL for Additional Product Inform Address:			rpnarma.c	<u>com</u>		1	Address 2:				Name:		Soma Raju 732-529-042	22		
City:	Piscataway	tennial Ave, Suite 1				State:				Number:   732-529-0423						
Key Contact:	Customer Service					Email:	customerservice@camberpharma.com			Strong E-mail.						
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regulations for product in any states?				No			
Product Therapeutic Classificatio	n:	N-methyl-D-	-aspartate	(NMDA) receptor antagoni	ist					' I	Special returns requiren	ents for this product?			No	
Tributing 2 departure (minery) receptor unargonist NO																
	ADDIT	IONAL PROD	UCT INFO	ORMATION			PRODUCT	DESCRIP	TION INFORMATION	d. Store prod	uct (unit of sale) upright	?			No	]
The product is?				Is the Product	Direct-Ship (	Only					Protect product (unit o	f sale) from light?			No	1
a legend device?		No		Is the Product	Unit of Use		Size:	60	0 ct	e. Shelf life:					24	Months
if yes, enter class #				Orphan Drug Status			Size.				Initial shelf life at laun	ch (if different):				Months
a product kit?		No					Strength:	10	0 mg							
if yes, list NDCs of				FDA Approval Status				_				ORDER INFORM	MATION			
component parts reverse numbered?		NI.	-				Dosage For	m: F	ilm coated tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	-	Allergens Present							x Bottle		1 Bottle of 6		unitr	
latex-free?		Yes	-					M	Modified capsule,		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes		Dairy, Lactose, Case	in, Dye, Corn,	Alcohol	Product Sha		iconvex		Ampule		, , , ,		,	
correctional institution block?		No					Product Col	G. G	Gray		Glass		Minimum o	rder quantity	?	Yes
opioid?		No					Froduct Col				Tube					
Cannabinoid?		No		Country of Origin	India		Product Imp		ebossed with 'J' on one side & 8' on the other side		Vial Liquid Sg					
If Unit Dose, is item bar coded to u	unit dose for								o on the other side		Vial Liquid Mu			many of whi	ch package t	type?
hospital scanning? If Unit Dose, indicate NDC here:				Is this product covered u Trade Agreements Act (T		No					Vial Powder S Vial Powder M		24	Each Inner/Carton	/Deals	
Il Onit Dose, indicate NDC here:				rrade Agreements Act (1	AA)!	NO					Other: Write Ir			Case	Pack	
			-	FOR GENERIC DRUG PRO	ODUCTS		!				Outer. Write ii			Joase		
			•	OR GENERIO DROGT R	000010											
						Au	thorized Generic	*If Autho	orized Generic, other			PHARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB							section f	fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharma	acv:	
II. Generic Equivalent to What Brand?: Namenda								Each								
								(Write-in, e.g	. 1 Vial)			Gram				
		DRUG	SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				HCPCS J-Co	de:			Milliliter		
Does supplier meet DSCSA defini	tion of manufactur	15053		Yes	_	GLN:	0331722498975				r	TEM AND PACKING I	NEOPMATIO	N		
Is product exempt from DSCSA?	ition of manufactu	ilei :		No No	-	GLN.	0331722496973					LW AND I ACKING I	NI OKWATIO	N.		
If yes, select exemption:						GCP:						Dimensi	ions (US msn	nte \	Volume	Saleable #
Other exemption - Write in:						GCF.					Weight Lbs	. Depth	Width	Height	(Cube)	Pieces
Is product repackaged?				No		If ves. was or	iginal product pur	rchased		Item/Each:						
Is product sold by manufacturer's	exclusive distrib	utor?		Yes		direct from m					0.75	1.52	1.52	2.54	5.87	1
Has FDA granted waiver/exceptio		roduct?		No		Provide source	ce manufacturer fo	or repacka	aged product	Box/Carton/E	Bundle/					
If yes, attach documentation from	m FDA.									Inner Pack:						
			CTIN	AND HIBCC PRODUCT IN	JEODMATION					Case:	2.25	9.75	6.75	4	263.25	24
			GIIN	AND HIBCC PRODUCT II	NFORMATION					Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable		HIBCC		GTII	N-14		Unit of Use GTIN-14	r anet.						
	= 1-9()	Quantity														
x Item/Each	N	1				003	31722808606		00331722808606							
Box/Carton/Bundle/Inner Pack											COST INFORMATION	ON		WHOLESAL	ER USE ONL	.Y:
X Case	N	24				203	31722808600						1			
Pallet			-					_		Regular Cost			Vendor #:			
			-					_		Invoice Cost	(VVAC) (\$)	\$8.60	Whsl. Code Fineline Co			
			-							As of date:	12/1/2024		I memie Co	uc.		
										. 10 01 00101			1			
			-										1			
			A	Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza	rd letter, PACKAGE	E INSERT,	LABEL AND PHOTO OF P	RODUCT PACK	AGING and BARCODE.					
	ormation on page								ted Dron Shin Only							



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):								
a. Cytotoxic?	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive							
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No							
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:							
(If yes, attach SDS with special instructions.)	NFPA Storage Level:							
e. Does the product contain DEHP?								
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?							
(if yes, answer a-e below and provide SDS)	If yes, indicate which:							
a. UN/Identification Number	ii yes, indicate which.							
b. Proper Shipping Name								
c. DOT Hazard Class	Hazardous Waste Identification							
d. Packing Group								
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics							
, ,	REMS or REGISTRY RESTRICTIONS							
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMOUT REGISTRY RESTRICTIONS							
	Is there a REMS on this product?							
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?							
d. Packing Group	Website URL:							
e. Inhalation Hazard?	Website UKL.							
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No							
Passenger	Limited Distribution Requirement							
Cargo	Comments / Details: (For example, iPledge program?)							
Passenger & Cargo								
Is this a reportable quantity? No	REMS: No							
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:							
No (if yes, identify method below)	Provider Name: DEA #:							
Limited Quantity	Site Enrollment Number assigned NCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)	Comments							
Special Permit; DOT-SP	Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#	Registry: No							
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:							
ADD'L STORAGE INFORMATION	Comments							
Is the Product								
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS							
Controlled by State(s)? No Listed Chemical (List I or II) No								
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647							
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:							
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com							
Restricted to retail pharmacy only:  No								
	Special regulations or returns requirements for this product in certain states?							
Restricted to hospital, clinics, and physician offices only:  No	INU							
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?							
Comments:								
MISCELLANEO	DUS NOTES and/or Image of Product Barcode:							



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

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#### 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:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday						
	Priority Overnight receipt available:						
Class of Trade Restriction:  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:	PO Receipt Cut off time:  Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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?						
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						