

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

Version 2021						Introduction Type	: New Item		x Final Version			Date:	1/27/	7/2023
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application	: ANDA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN			ce):	20	4389			a. romporata	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica									,					
DUNS:	82-677-4775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established Na	ame: Mema	antine Hydrochloride Tablets	10mg 60ct				T	(write in)	•				
Selling Unit NDC:	31722-808-60		Unit of Use NDC:			UPC: 33	1722808606		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Memantine Hydro	ochloride Tablets 10m	na					Ī	Is this product to be shippe	to customers on	ce?		No	1
			9						Is this product to be shippe				No	
Active Ingredient(s):		Memantine Hydroch	hloride								•			
		-						b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharma							Name:		Soma Raju			
Address:		Ave (and) 800 Center	nnial Ave, Suite 1			Address 2:			Number:		732-529-042			
City:	Piscataway				State:		ip: 08854		Group E-mail:		somaraju@h	eterousa.co	<u>m</u>	
Key Contact:	Customer Service	9			Email:	customerservice@ca	mberpharma.com							7
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	ulations for product in any				No	-
Product Therapeutic Classification	on:	NMDA Receptor An	itagonists						Special returns requirement	s for this product?			No	
	ADDIT	IONAL PROPUST IN	FORMATION			PROBLICT DES	ACRIPTION INFORMATION							7
	ADDITI	IONAL PRODUCT IN	FORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product			Size:	60ct	e. Shelf life:						Months
if yes, enter class #		1	Orphan Drug Status						Initial shelf life at launch (	if different):				Months
a product kit?		No	FDA 4			Strength:	10mg			ORDER INFORI	MATION			
if yes, list NDCs of			FDA Approval Status				Oral Solid - Tablet			OKDEK INFORI	MATION			
component parts reverse numbered?		No				Dosage Form:	Oral Solid - Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 60			
latex-free?		No	_				Modified Capsule		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No	Dairy, Lac	tose, Casein		Product Shape:			Ampule		, , , , ,	5	,	
correctional institution block?		No				Product Color:	Gray		Glass		Minimum or	der quantity	/?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Lower punch 'J' and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					r roduct imprint.	Upper Punch'48'		Vial Liquid Multi		If Yes, how		ich package t	type?
hospital scanning?		No	Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No				Vial Power Multi			Inner/Cartor	n/Pack	
									Other: Write In		Х	Case		
			FOR GENERIC DRUG PR	ODUCTS										
						alternation of Community with	Authorized Consideration		DI.	ARMACY ORDER	/ DILL LINET			
					AL		Authorized Generic, other ction fields are not applicable			ARMACT URDER				
I. Orange Book Rating:	AB						ction fields are not applicable	Rec. sell unit	to customer?		Rx billing u		acy:	
II. Generic Equivalent to What Bra	and?:	Namenda						OM/-ite in a se	4 1 (" - 1)			Each		
		DRIIG SUBBI	LY CHAIN SECURITY ACT	DSCSA) INFO	PMATION			(Write-in, e.g.	1 Vial)			Gram Milliliter		
		DRUG SUFFE	IT CHAIN SECONITT ACT	DSCSA) IN O	MATION							wiiiiitei		
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes		GLN:	0331722000000			ITEN	I AND PACKING I	NFORMATION	١		
Is product exempt from DSCSA?														
If ves. select exemption:					GCP:			1		Dimons	ions (US msm	nte l	Volume	Saleable #
Other exemption - Write in:					GUF.			1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was o	riginal product purchas	sed	Item/Each:		Берш			(Cabe)	
Is product sold by manufacturer's	s exclusive distrib	utor?	Yes	$\neg$	direct from n				0.1		1.5	2.5		1
Has FDA granted waiver/exception			No	7		ce manufacturer for re	packaged product	Box/Carton/B	undle/					
If yes, attach documentation fro	om FDA.							Inner Pack:						
								Case:	2.25	9.75	6.81	4		24
		GTI	IN AND HIBCC PRODUCT I	NFORMATION					2.20	5.76	0.01			24
								Pallet:						
Saleable Unit of Measure	5	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
		1			003	31722808606	00331722808606		OOOT INCODE ATION			MILOL FOR	ER USE ONL	V
X Item/Each		-							COST INFORMATION			WHOLESAL	EK USE ONL	10
Box/Carton/Bundle/Inner Pack														
Box/Carton/Bundle/Inner Pack X Case		24			203	31722808600		Boarder Cr.			Vander #			
Box/Carton/Bundle/Inner Pack					203	31722808600		Regular Cost	WAC) (\$)	¢42.00	Vendor #:	#-		
Box/Carton/Bundle/Inner Pack X Case					203	31722808600		Regular Cost Invoice Cost (	(WAC) (\$)	\$12.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case					203	31722808600		Invoice Cost (	WAC) (\$)	\$12.00				
Box/Carton/Bundle/Inner Pack X Case					203	31722808600			WAC) (\$)	\$12.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case					203	31722808600		Invoice Cost (	WAC) (\$)	\$12.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case			Attach copy of SAFETY D.	ATA SHEET (SI			SERT, LABEL AND PHOTO OF I	Invoice Cost ( As of date:		\$12.00	Whsl. Code			



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

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

A Control product   find an approximation   No   No   A Control program   Proposed control products   No   No   No   No   No   No   No   N	M.A.	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION		
Is the product a CA Prop 66 sentengen?  In the product a CA Prop 66 sentengen?  In the product a CA Prop 66 sentengen?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions?  In the product and CA Prop 66 sentengen intractions.  In the product and CA Prop 66 sentengen in	a. Cytotoxic?	No	SD	S Hazard Classification	
Service   The product require special clares unclose?   No	Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant?	Inorganic	Oxidizer		
of yes, narwer as bellow and provole SDS)  a. NNASomitions Number  b. Proper Shipping Name  c. ODT Hazard Class  d. Packing Group  fit yes, indicate which:    Packing Group	d. Does this product require special clean-up instructions?     (If yes, attach SDS with special instructions.)	No	identify NFPA Storage Level:		
d. Packing Group - Inhalation Hazard* - Inhalation Hazard* - Is this product regulated for shipment by IATA?  (if yee, aware a below and provides SSS) - a. UMSderification Number - C. DOT Hazard Class - C. Packing Group - Inhalation Hazard*	(if yes, answer a-e below and provide SDS) a. UN/Identification Number	No		No	
Enhalation Hzzard?   No   No   Inhalation Hzzard?   No   No   Inhalation Hzzard?   No   No   Inhalation Hzzard?   No   No   Inhalation Hzzard?   N			Haza	rdous Waste Identification	
The product regulated for shipment by WTA?  No  (If yes, answer are below and provide SDS)  a. UNKfernification Number  c. DOT Hazard Class  d. Packing Group  e. Initialistic Hazard?  St. Passenger  C. DOT Hazard Class  Is there a REMS on this product?  If yes, is it managed with a pharmacy registry?  Wester United Destribution Requirement  Comments  If yes, it is managed with a pharmacy registry?  Wester United Destribution Requirement  Comments  REMS Program Manager Name:  REMS Program Manager Name:  REMS Program Manager Name:  REMS Program Manager Name:  Septiment Comments (Perialist (For example, iPledge program?)  No Brail Quantity (40 CFR 173.4)  Special Provision (tisted in Column 7 of 49 CFR 172.101):  Special Provision (tisted in		NI-	EDA Harandous Mosto Cada		Wasta Charastaristics
(if yes, answer a~ below and provide SDS) a. UNIdentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group l. Inhalation Hazard?  B. Stee product restricted for air shipment? If so, indicate restriction:  No B. Same a reportable quantity?  Is this a responsible quantity?  Is the product restricted for air shipment? If so, indicate restriction:  Is this a responsible quantity?  Is this a reportable quantity?  Is this a responsible quantity?  Is this a reportable quantity?  Is this a reportable quantity?  Is this a reportable quantity?  Is this product hispode utilizing an authorized DOT exception or Special Permit?  Is this product hispode utilizing an authorized DOT exception or Special Permit?  Is the product.  Special Provision (fiside in Column 7 of 49 CFR 172.101);  Spe			EPA Hazardous Waste Code:		waste Characteristics
a. UM/dentification Number b. Proper's Nigriping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?		No	REMS o	REGISTRY RESTRICTIONS	
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?   No the product restricted for all xhipment? If so, indicate restriction:   Passenger   Cargo   Passenger   Pa			KEMBO	TRESISTRI RESTRICTIONS	
d. Pasking Group   Institute Districted for air shipment? If so, indicate restriction:   Pasking R Cargo   Pasking R Car			· ·	No	
e. Inhalation Hazard?   S the product restricted for air shipmen? If so, indicate restriction:   Passenger   Cargo   Passenger & Cargo   Passenger					
Is the product restricted for air shipment? If so, indicate restriction:    Passenger   Passenger & Cargo		No	Website URL:		
Passenger   Cargo   Passenger & Passenger & Cargo   Passenger & Passenge			Med Guide Required		
REMS:		110	I ·		
REMS: No   Phone:			Comments / Details: (For example, iPledge program?)	·	
RCM Threshold: Is this a martine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit; Ornsumer Commodity, ORM-D Small Quantity (49 CFR 173-4) Special Provision (listed in Column 7 of 49 CFR 172-101); SP#  ADD'L STORAGE INFORMATION  Is the Product Controlled Substance? No If yes, incidate which: Is a scheduled listed chemical product?: No If yes, incidate which: Is a scheduled listed chemical product?: No Restricted to retail pharmacy, hopate, derice and physician offices only: Restricted to retail pharmacy, hopate, derice and physician offices only: Restricted to retail pharmacy hopate, derice and physician offices only: Restricted to retail pharmacy hopate, derice and physician offices only: Restricted to retail pharmacy hopate, derice and physician offices only: Restricted for uSt territories? (explain in comments)  No Restricted to retail pharmacy hopate, derice and physician offices only: Restricted to retail pharmacy hopate, derice and physician offices only: Restricted to retail pharmacy hopate, derice and physician offices only: Restricted to retail pharmacy hopate, derice and p					
Is this product shipped utilizing an authorized DOT exception or Special Permit?    Initial Quantity				No	2
Is this product shipped utilizing an authorized DOT exception or Special Permit?  (if yes, identify method below)  Limited Quantity Consumer Commodity, QRM-D Small Quantity (49 CFR 173.4) Special Provision (listed in Column 7 of 49 CFR 172.101); Sp					Phone:
Limited Quantity Consumer Commodity, ORM-D Consumer Commodity, ORM-D Special Provision (listed in Column 7 of 49 CFR 172.101);  Special Provision (listed in Column 7 of 49 CFR 172.101);  SP#					
Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR 172.101); Special Provision (listed in Column 8 of 49 CFR					
Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Substance? Controlled Substance? Controlled Substance? No Listed Chemical (List 1 or II) ARCOS Reportable? Schedule No. Is it a scheduled listed chemical product?: No restricted to retail pharmacy only: Restricted to retail pharmacy only: Restricted from US territories? (explain in comments)  Comments:  Comments  Registry Program Contact Name: Comments  Registry Program Contact Name: Comments  No If yes, incide admaged: Is product received damaged: Is product					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#			by Supplier:		NPI#.
Registry:   Registry Program Contact Name:   Phone:			Comments		
Registry Program Contact Name: Phone:    Sthe Product	Special Provision (listed in Column 7 of 49 CFR 172.101);				
Is the Product Controlled Substance? No Controlled Substance Code Listed Chemical (List I or II) ARCOS Reportable? Schedule No.  CLASS OF TRADE RESTRICTION:  No restriction: Select YES # 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:  Comments  Comments  Comments  Comments  RETURN INSTRUCTIONS  Contact tel. # if product received damaged:   1-866-827-3647     15 product returnable for credit:   17 yes     18 product returns policy:   18 p	SP#				
Is the Product  Controlled Substance? Controlled Substance? Controlled Substance? Controlled Substance? No ARCOS Reportable? Schedule No.  No If yes, indicate which: Is it a scheduled listed chemical product?: No Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)  Comments:    Controlled Substance Code	ADDIL STOPAGE INFORMATION				Phone:
Controlled Substance? Controlled Substance? Controlled Substance Code Listed Chemical (List I or II) ARCOS Reportable? Schedule No.  Schedule No.  CLASS OF TRADE RESTRICTION:  No restriction: Select YES if sold to retail pharmacy, hospitals, clinics, and physician offices only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)  Comments:  Controlled Substance Code Listed Chemical (List I or II) No No No Controlled Substance Code Listed Chemical (List I or II) No No Controlled Substance Code Listed Chemical (List I or II) No No Controlled Substance Code Listed Chemical (List I or II) No No If yes, indicate which: Is it a scheduled listed chemical product?: No URL/Link to returns policy:  URL/Link to returns policy:  Contact - customerservice@camberpharma.com  Special regulations or returns requirements for this product in certain states?  No If so, which states? Other requirements? Comments?  If so, which states? Other requirements? Comments?			Continents		
Controlled by State(s)? ARCOS Reportable? Schedule No.  Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: Is it a scheduled listed chemical product?: Is product received damaged: Is product returnable for credit: URL/Link to returns policy:  Contact - customerservice@camberpharma.com  Special regulations or returns requirements for this product in certain states? Restricted from US territories? (explain in comments)  Comments:  Comments:  Listed Chemical (List I or II) No If yes, indicate which: Is product received damaged: Is product returnable for credit: URL/Link to returns policy:  Contact - customerservice@camberpharma.com  Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?  If so, which states? Other requirements? Comments?			RI	ETURN INSTRUCTIONS.	
ARCOS Reportable? Schedule No.  If yes, indicate which: 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  Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)  Comments:  On the yes, indicate which: Is it a scheduled listed chemical product?: No  URL/Link to returns policy:  URL/Link to returns policy:  Special regulations or returns requirements for this product in certain states?  No  If yes, indicate which: Is product received damaged: Is product recei		No			
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:  URL/Link to returns policy:  contact - customerservice@camberpharma.com  Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?  If so, which states? Other requirements?			Contact tel. # if product received damaged:	1-866-827-3647	
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)  No Comments:  Comments:  Yes  No		No		Yes	
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No  No  If so, which states? Other requirements? Comments?	CLASS OF TRADE RESTRICTION:				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)  No No If so, which states? Other requirements? Comments?	No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	contact - customerse	rvice@camberpharma.com	
Restricted from US territories? (explain in comments)  Comments:  If so, which states? Other requirements? Comments?	Restricted to retail pharmacy only:	No			
Comments:		'	No		
	,	No	If so, which states? Other requirements? Comments?		
MISCELLANEOUS NOTES and/or Image of Product Barcode:	Comments:				
MISCELLANEOUS NOTES and/or Image of Product Barcode:					
		ISCELLANEC	OUS 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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:		Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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? Is product order for restocking purposes?