

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

						Introduction Type	pe: New Item		x	Final Version			Date:	6/23/	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Applicatio	n: ANDA	a. Tem	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN			e);	21	0354					ature Range	Controlled Room -		and 25 C (68°	, – 77° F)	
Medical Device Class, if applical			<u>, </u>												
DUNS:	11-856-3719								Other Te	emperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Methylp	henidate Hydrochloride Ch	ewable Tablets	USP 2.5 mg				(w	rite in)	•				
Selling Unit NDC:	31722-926-01		Unit of Use NDC:			UPC: 3	331722926010		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Methylphenidate	Hydrochloride Chewabl	le Tablets, USP 2.5 mg						Is this p	roduct to be shipped	to customers on ic	e?		No	1
,	,	,	,							roduct to be shipped				No	1
Active Ingredient(s):		Methylphenidate hyd	rochloride, USP									•			
								b. Con	b. Contact for temperature excursion questions:						
URL for Additional Product Inform		www.camberpharma.	com						Name:			Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:			Number			732-529-042			
City:		iscataway State:				Zip: 08854		Group E-mail: somaraju@heterousa.com							
Key Contact:	1-866-827-3647				732-562-8788	camberpharma.com		c. Special regulations for product in any states? *Ye				*)/	1		
Phone Number:		Control noncour aunt	am (CNC) atimulant		Fax:	132-302-0100		c. Spe						*Yes	
Product Therapeutic Classificatio	n:	Central nervous systematics	em (CNS) stimulant						Special	returns requirement	s for this product?			*Yes	
	ADDIT	IONAL PRODUCT INF	ODMATION			BRODUCT DE	SCRIPTION INFORMATIO	N		- (1-)!!10				NI.	1
	ADDIT	UNAL PRODUCT INF		-		PRODUCT DE	SCRIPTION INFORMATIO	d. Sto	ore product (unit					No	1
The product is?			Is the Product	Direct-Ship (Only					product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. She						24	Months
if yes, enter class #		N.	Orphan Drug Status				2.5		Initial s	helf life at launch (i	if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	2.5 mg				ORDER INFORM	IATION			
component parts			FDA Approvai Status				Chewable tablet				ORDER IN ORM	ATION			
reverse numbered?		No				Dosage Form:	Officwable tablet		Unit of	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x	Bottle		1 Bottle of 10			
latex-free?		Yes	Lactose, Dairy, Corn,	Alcohol, Anima	al, Sugar,	Product Shape	Round, beveled edge			Box/Carton		(Write-in, e.		Vials)	
preservative-free?		Yes	Rennet, Ca	ssein, Whey		Product Snape	# ·			Ampule					
correctional institution block?		No				Product Color:	White to off-white			Glass		Minimum or	der quantity	?	Yes
opioid?		No				r roduct color.				Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprir	nt: Debossed with '260' on one and 'AT' on the other side	e side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for						and AT off the other side			Vial Liquid Multi				ch package t	type?
hospital scanning?			Is this product covered u							Vial Powder Sgl		24	Each	-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	Yes					Vial Powder Multi Other: Write In			Inner/Carton/ Case	Pack	
			FOR GENERIC DRUG PR	ODUCTO						Other, write in			Case		
			FOR GENERIC DRUG FR	ODUCIS											
									PHARMACY ORDER / BILL UNIT						
					Διι	thorized Generic *	If Authorized Generic other			PH	ARMACY ORDER	/ BILL UNIT			
I Communicate Designation	AD				Au		If Authorized Generic, other section fields are not applica		call unit to aucto		ARMACY ORDER				
I. Orange Book Rating:	AB	Methylia Chaushla			Au		If Authorized Generic, other section fields are not application		sell unit to custo		ARMACY ORDER	/ BILL UNIT		cy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Methylin Chewable			Au			Rec. s			ARMACY ORDER		Each	ıcy:	
			CHAIN SECURITY ACT (DSCSA) INFO				Rec. s	sell unit to custo e-in, e.g. 1 Vial)		ARMACY ORDER		Each Gram	ıcy:	
			CHAIN SECURITY ACT	DSCSA) INFO				Rec. s			ARMACY ORDER		Each	icy:	
	and?:	DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFO				Rec. s		mer?	ARMACY ORDER	Rx billing u	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPLY		DSCSA) INFO	RMATION			Rec. s		mer?		Rx billing u	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	DRUG SUPPLY	Yes	DSCSA) INFO	RMATION			Rec. s		mer?	I AND PACKING IN	Rx billing u	Each Gram Milliliter	volume	Saleable #
II. Generic Equivalent to What Bra	and?:	DRUG SUPPLY	Yes	DSCSA) INFO	RMATION GLN:			Rec. s		mer?	I AND PACKING IN	Rx billing u	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPPLY	Yes	DSCSA) INFO	RMATION GLN: GCP:		section fields are not applica	Rec. s	e-in, e.g. 1 Vial)	ITEM Weight Lbs.	I AND PACKING IN Dimensie Depth	Rx billing un	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	und?:	DRUG SUPPLY	Yes No No Yes	DSCSA) INFO	RMATION GLN: GCP:	0860000397957	section fields are not applica	Rec. s (Write	e-in, e.g. 1 Vial)	mer?	I AND PACKING IN	Rx billing un	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	ition of manufactu s exclusive distrib	DRUG SUPPLY	Yes No	DSCSA) INFO	GLN: GCP: If yes, was or direct from m	0860000397957	section fields are not applicate	Rec. s (Write	e-in, e.g. 1 Vial) Each: Carton/Bundle/	ITEM Weight Lbs.	I AND PACKING IN Dimensie Depth	Rx billing un	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
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II. Generic Equivalent to What Bra Does supplier meet DSCSA definition is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation fro Saleable Unit of Measure X Item/Each	ition of manufactu s exclusive distrib n/exemption for p m FDA.	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity	No No Yes No AND HIBCC PRODUCT I		GLN: GCP: If yes, was or direct from m Provide sour	0860000397957 riginal product purch fir? ce manufacturer for i	ased repackaged product	Rec. s (Write	e-in, e.g. 1 Vial) Each: Carton/Bundle/ Pack: :	Weight Lbs. 0.08 1.85	Dimension Depth 1.56	Rx billing under the state of t	Each Gram Milliliter ts.) Height 2.94	Volume (Cube) 7.16 241.92	Pieces 1 24
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each Box/Carton/Bundle/Inner Pack	ition of manufactu s exclusive distrib n/exemption for p m FDA.	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity 1	No No Yes No AND HIBCC PRODUCT I		GLN: GCP: If yes, was or direct from m Provide sour	0860000397957 Oscillation of the communication of	ased repackaged product	Rec. s (Write	e-in, e.g. 1 Vial) Each: Carton/Bundle/ Pack: :	Weight Lbs. 0.08 1.85	Dimension Depth 1.56	Rx billing under the state of t	Each Gram Milliliter ts.) Height 2.94	Volume (Cube) 7.16 241.92	Pieces 1 24
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ZARD 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						
Does the product abor boar a of those warming.	Solida 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?	14 1 A Giolage Level.						
·							
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							
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?							
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number							
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?							
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo	Constitution of Details. (For example, in ledge program.)						
	DEMO.						
Is this a reportable quantity? No RQ Threshold:	REMS: No REMS Program Manager Name: Phone:						
Is this a marine pollutant? No							
Is this a manner politicalit? NO Second Permit?	Supplier Manages REMS registry exclusively: 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)	by Supplier.						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments						
SP#	Registry: No						
Sr#							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments						
	Connents						
Is the Product							
Controlled Substance? Yes Controlled Substance Code 1724	RETURN INSTRUCTIONS						
Controlled by State(s)? Yes Listed Chemical (List I or II) No							
ARCOS Reportable? Yes If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. 2 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	165						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part	-						
Giorage of this product flust ablue by the lederally mandated DEA requirements obtilitied in 21 GFR Part	1501.72. Frientykeitoriunios. Contains Frientykidalinie 0.33 mg per tablet.						



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?