

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

						Introduction	Type:	New Item	]	x Final Version			Date:	6//23	/2024		
			PRODUCT INFORMAT	ION						SPECIAL HANI	DLING AND STOR	AGE REQUIF	REMENTS*				
Company Name:	Camber Pharmaceu	uticals Inc				Applica	tion:	ANDA	a Temperatur	e - Indicate the USP tempe	erature range for t	his product					
Application Number for NDA/AN			ice).	21	5523	7 (6)		7.11.071		Temperature Range	Controlled Room -		and 25 C (68	3° – 77° F)			
Medical Device Class, if applical										p							
DUNS:	11-856-3719								1	Other Temperature Range I	Requirement	Excursions p	ermitted bet	ween 15°C a	nd 30°C		
Proprietary Name (If Applicable) a	and Established Nam	ne: Dexm	ethylphenidate Hydrochloride	Extended-Rele	ease Capsules 1	I0 mg			1	(write in)		(59°F to 86°F					
Selling Unit NDC:	31722-230-01		Unit of Use NDC:			UPC:	33172223001	8		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Dexmethylphenidate	e Hydrochloride Ext	tended-Release Capsules 10	) mg					1	Is this product to be shipped	d to customers on ic	ce?		No			
Is this product to be shipped to customers on dry ice? No																	
Active Ingredient(s): Dexmethylphenidate hydrochloride																	
b. Contact for temperature excursion questions:																	
URL for Additional Product Inform		www.camberpharma.com				Address 2.						Soma Raju					
Address:	800 Centennial Ave,	e, Suite 1			01-1-1	Address 2:  N.J Zip: 08854		Number:			732-529-0423 somaraju@heterousa.com						
City:	Piscataway Customer Service	State			Email:		Zip: 0885			Group E-mail:		somaraju@r	ieterousa.coi	<u>n</u>			
Key Contact: Phone Number:	1-866-827-3647				Fax:	customerservice@camberpharma.com 732-562-8788		c. Special regulations for product in any states?					*Yes				
Product Therapeutic Classificatio		Central nervous system (CNS) stimulant			- I ux.	732-302-6760			c. opeciai regi	Special returns requirement				*Yes			
r roduct merapeutic classificatio		Jentiai neivous sys	sterri (CNO) stirridiarit							Special returns requirement	s for this product?			162			
	ADDITION	NAL PRODUCT INF	FORMATION			PRODUCT	DESCRIPTION	INFORMATION	d Store produ	ct (unit of sale) upright?				No			
<b>T</b>	ADDITION	ALTRODOOT IN		Discot Ohio (	Sel.	TRODUCT	DEGOIGH HOR	IN ORMATION	u. Store proud								
The product is? a legend device?	Ī.	No	Is the Product Is the Product	Direct-Ship ( Neither	Jrily		100 ct		e. Shelf life:	Protect product (unit of sa	ale) from light?			No 24	Months		
if yes, enter class #	P	NO	Orphan Drug Status	Neither		Size:	100 Ct			Initial shelf life at launch (	if different):	24		24	Months		
a product kit?	1	No	Orphan Drug Glatas				10 mg			initial shell life at launon (	ii dinerenty.			Monais			
if yes, list NDCs of	·	10	FDA Approval Status			Strength:	109				ORDER INFORM	IATION					
component parts						Docago For	Extend	ded-release, hard									
reverse numbered?	1	No				Dosage For	gelatir	capsule		Unit of Sale		What is the	NDC selling	unit?			
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 10					
latex-free?		Yes	Corn, Alcohol,	Animal, Suga	r	Product Shape: Capsule			Box/Carton			(Write-in, e.	g. 1 Box of 1	ປ Vials)			
preservative-free?		Yes	, , , , , , , , , , , , , , , , , , , ,	. ,		·				Ampule			_				
correctional institution block?		No				Product Co		opaque cap and		Glass		Minimum or	der quantity	/?	Yes		
opioid? Cannabinoid?		No No	Country of Origin	USA			Imprinte	opaque body ed with 'M10' on cap	Tube Vial Liquid Sgl								
If Unit Dose, is item bar coded to u		NO	Country of Origin	USA		Product Imp		on body in black ink		Vial Liquid Multi		If Yes, how	many of wh	ich nackade	type?		
hospital scanning?	Till dose for		Is this product covered un	nder the						Vial Powder Sgl			Each	cii package	туре:		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		Yes					Vial Powder Multi			Inner/Cartor	/Pack			
			_ `							Other: Write In			Case				
			FOR GENERIC DRUG PRO	DDUCTS													
			-									-					
					Λ	horized Generic	*If Authorized	Ceneric other		DI I							
I. Orange Book Rating:					Aut		/	Generic, other		PH.	ARMACY ORDER	/ BILL UNIT			Rx billing unit to pharmacy:		
II. Generic Equivalent to What Bra	AB				Aut			are not applicable	Rec. sell unit t		ARMACY ORDER		nit to pharm	acy:			
		Focalin XR			Aut				Rec. sell unit t		ARMACY ORDER		nit to pharm Each	acy:			
4									Rec. sell unit t	to customer?	ARMACY ORDER		Each Gram	acy:			
•			Y CHAIN SECURITY ACT (E	DSCSA) INFOR						to customer?	ARMACY ORDER		Each	acy:			
	and?: F	DRUG SUPPLY	,	OSCSA) INFOR	RMATION					to customer?	]	Rx billing u	Each Gram Milliliter	асу:			
Does supplier meet DSCSA defini	and?: F	DRUG SUPPLY	Yes	DSCSA) INFOR		0860000397957				to customer?	ARMACY ORDER	Rx billing u	Each Gram Milliliter	асу:			
Does supplier meet DSCSA defini	and?: F	DRUG SUPPLY	,	DSCSA) INFOR	RMATION GLN:					to customer?	AND PACKING IN	Rx billing u	Each Gram Milliliter				
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	and?: F	DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION					to customer?	AND PACKING IN	Rx billing under the second se	Each Gram Milliliter	Volume	Saleable #		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?: F	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN:	0860000397957			(Write-in, e.g.	to customer?  1 Vial)	AND PACKING IN	Rx billing u	Each Gram Milliliter		Saleable #		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: F	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or	0860000397957				to customer?  1 Vial)	AND PACKING IN	Rx billing under the second se	Each Gram Milliliter	Volume			
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	and?: F	DRUG SUPPLY	Yes No No Yes	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	0860000397957	section fields	are not applicable	(Write-in, e.g.	to customer?  1 Vial)  TEM  Weight Lbs.  0.1	AND PACKING IN Dimensio Depth	Rx billing under the second se	Each Gram Milliliter	Volume (Cube)	Pieces		
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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	ition of manufacture s exclusive distribute n/exemption for production	DRUG SUPPLY er?  cor? bduct?  GTIN leable Quantity	Yes No No Yes No Yes No		GLN: GCP: If yes, was or purchased direction purchased direction of the control o	0860000397957  Iginal product rect from mfr? 2e manufacturer 1 4-14 11722230018	section fields	are not applicable	(Write-in, e.g.  Item/Each:  Box/Carton/Bu Inner Pack: Case:	TEM Weight Lbs.  0.1	AND PACKING IN  Dimension Depth  2	Rx billing under the second se	Each Gram Milliliter htts.) Height 3.5	Volume (Cube)	Pieces  1  24		
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD 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							
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 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?  No (if yes, identify method below)	Wholesale distributor support:  Provider Name:  DEA #:						
No (if yes, identify method below)  Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)	бу барыст.						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
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:						
	contact - customerservice@camberpharma.com						
	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:	product in certain states?						
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.						
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR F	art 1301.72.						



## **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  Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO:  Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	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, 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:  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:	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?