



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 11/14/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 211009				NDA 505(b) Type: NOT APPLICABLE			
Medical Device Class, if applicable:							
DUNS: 11-856-3719							
Proprietary Name (If Applicable) and Established Name: Methylphenidate Hydrochloride Extended-Release Tablets, USP 54 mg							
Selling Unit NDC: 31722-955-01				Unit of Use NDC:			
UDI				UPC: 331722955010			
CVX Code:				MVX Code:			
Description: Methylphenidate Hydrochloride Extended-Release Tablets, USP 54 mg							
Active Ingredient(s): Methylphenidate hydrochloride, USP							
URL for Additional Product Information: www.camberpharma.com							
Address: 800 Centennial Ave, Suite 1				Address 2:			
City: Piscataway				State: NJ			
Key Contact: Customer Service				Zip: 08854			
Phone Number: 1-866-827-3647				Email: customerservice@camberpharma.com			
Product Therapeutic Classification: Central nervous system (CNS) stimulant				Fax: 732-562-8788			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		100 ct	
a legend device?		Is the Product...		Strength:		54 mg	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Extended-release, film coated tablet	
a product kit?				Product Shape:		Round, cylindrical, biconvex	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:		Light to dark brown	
reverse numbered?				Product Imprint:		Printed with '215' in black ink	
co-licensed?		Allergens Present					
latex-free?		Dye, Corn, Alcohol					
preservative-free?		Country of Origin		USA			
correctional institution block?							
opioid?							
Cannabinoid?							
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?		Yes			
If Unit Dose, indicate NDC here:							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB				Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Concerta							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?				GLN: 0843368117603			
Is product exempt from DSCSA?				GCP:			
If yes, select exemption:				If yes, was original product purchased direct from mfr?			
Other exemption - Write in:				Provide source manufacturer for repackaged product			
Is product sold by manufacturer's exclusive distributor?							
Has FDA granted waiver/exception/exemption for product?							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)		Saleable Quantity		HIBCC	
Item/Each		N		1		GTIN-14	
Box/ Carton/ Bundle/ Inner Pack		N		24		Unit of Use GTIN-14	
Case		N		24		00331722955010	
Pallet		N		24		10331722955017	
ITEM AND PACKING INFORMATION							
Weight Lbs.		Dimensions (US msmts.)		Volume (Cube)		Saleable # Pieces	
Depth		Width		Height			
Item/Each:		0.18		2.02		3.40	
Box/ Carton/ Bundle/ Inner Pack:		12.5		8.5		403.75	
Case:		4.7		3.8		24	
Pallet:							
COST INFORMATION							
Regular Cost				WHOLESALE USE ONLY:			
Invoice Cost (WAC) (\$)				Vendor #:			
As of date: 9/1/2021				Whsl. Code #:			
				Fineline Code:			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

*Please provide any additional information on page 2.



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen?
Is the product a CA Prop 65 reproductive toxicant?
Does the product label bear a CA Prop 65 warning?

- c. Contact Hazard?
- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

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
- e. Inhalation Hazard?

Is this product regulated for shipment by IATA?
(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:

- Passenger
 Cargo
 Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- (if yes, identify method below)
- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

ADD'L STORAGE INFORMATION

Is the Product...

- | | | | |
|-------------------------|----------------------------------|---|-----------------------------------|
| Controlled Substance? | <input type="text" value="Yes"/> | Controlled Substance Code | <input type="text" value="1724"/> |
| Controlled by State(s)? | <input type="text" value="Yes"/> | Listed Chemical (List I or II) | <input type="text" value="No"/> |
| ARCOS Reportable? | <input type="text" value="Yes"/> | If yes, indicate which: | <input type="text"/> |
| Schedule No. | <input type="text" value="2"/> | Is it a scheduled listed chemical product?: | <input type="text" value="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:

SDS Hazard Classification

- | | |
|---|---|
| ☒ Organic | <input type="text" value="Corrosive"/> |
| ☐ Inorganic | <input type="text" value="Oxidizer"/> |
| ☐ Steroid/Androgen | <input type="text" value="Contact Hazard"/> |

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

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

Registry:

Registry Program Contact Name:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

1-866-827-3647

Is product returnable for credit:

Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?

Yes

If so, which states? Other requirements? Comments?

DEA Form 222 or its electronic equivalent is required for all returns in all states.

MISCELLANEOUS NOTES and/or Image of Product Barcode:

*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.

Release DATE



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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: Fax Number: Fax Number: Phone No.: Site Address:	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: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: ☐ PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: ☐ PO Receipt Cut off time: Saturday Overnight receipt available: ☐ PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: ☐ Other fees apply: ☐
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:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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? ☐