



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

Version 2021 Introduction Type: New Item Final Version Date: 7/18/2024

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: Camber Pharmaceuticals, Inc. **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 211009
Medical Device Class, if applicable:
DUNS: 11-856-3719
Proprietary Name (If Applicable) and Established Name: Methylphenidate Hydrochloride Extended-Release Tablets, USP 27 mg
Selling Unit NDC: 31722-953-01 **Unit of Use NDC:** **UPC:** 331722953016
UDI **CVX Code:** **MXV Code:**
Description: Methylphenidate Hydrochloride Extended-Release Tablets, USP 27 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 **Zip:** 08854
Key Contact: Customer Service **Email:** customerservice@camberpharma.com
Phone Number: 1-866-827-3647 **Fax:** 732-562-8788
Product Therapeutic Classification: Central nervous system (CNS) stimulant

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)
 Other Temperature Range Requirement (write in):
 Notes:
 Is this product to be shipped to customers on ice? No
 Is this product to be shipped to customers on dry ice? No
b. Contact for temperature excursion questions:
Name: Soma Raju
Number: 732-529-0423
Group E-mail: somaraju@heterousa.com
c. Special regulations for product in any states? *Yes
 Special returns requirements for this product? *Yes
d. Store product (unit of sale) upright? No
Protect product (unit of sale) from light? No
e. Shelf life: 24 Months
 Initial shelf life at launch (if different): Months

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|------------------------------|---|---|
| The product is a legend device? if yes, enter class # | <input type="checkbox"/> No | Is the Product... Direct-Ship Only | <input type="checkbox"/> |
| a product kit? if yes, list NDCs of component parts reverse numbered? | <input type="checkbox"/> No | Is the Product... Orphan Drug Status | <input type="checkbox"/> Neither |
| co-licensed? | <input type="checkbox"/> No | FDA Approval Status | <input type="text"/> |
| latex-free? | <input type="checkbox"/> No | Allergens Present | <input type="text"/> |
| preservative-free? | <input type="checkbox"/> Yes | Dye, Corn, Alcohol | <input type="text"/> |
| correctional institution block? | <input type="checkbox"/> No | Country of Origin | <input type="text"/> USA |
| opioid? | <input type="checkbox"/> No | Is this product covered under the Trade Agreements Act (TAA)? | <input type="checkbox"/> Yes |
| Cannabinoid? | <input type="checkbox"/> No | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="checkbox"/> | | |
| If Unit Dose, indicate NDC here: | <input type="text"/> | | |
| | | Size: | <input type="text"/> 100 ct |
| | | Strength: | <input type="text"/> 27 mg |
| | | Dosage Form: | <input type="text"/> Extended-release, film coated tablet |
| | | Product Shape: | <input type="text"/> Round, cylindrical, biconvex |
| | | Product Color: | <input type="text"/> Light pink to pink |
| | | Product Imprint: | <input type="text"/> Printed with '213' in black ink |

ORDER INFORMATION

| Unit of Sale | What is the NDC selling unit? |
|--|---|
| <input checked="" type="checkbox"/> Bottle | <input type="text"/> 1 Bottle of 100 Tablets |
| <input type="checkbox"/> Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | |
| <input type="checkbox"/> Glass | |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | |
| <input type="checkbox"/> Vial Liquid Multi | |
| <input type="checkbox"/> Vial Powder Sgl | |
| <input type="checkbox"/> Vial Powder Multi | |
| <input type="checkbox"/> Other: Write In | |
| | Minimum order quantity? <input type="checkbox"/> Yes |
| | If Yes, how many of which package type? |
| | <input type="text"/> 24 Each |
| | <input type="text"/> Inner/ Carton/ Pack |
| | <input type="text"/> Case |

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB

II. Generic Equivalent to What Brand?: Concerta

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes

Is product exempt from DSCSA? No

If yes, select exemption: Other exemption - Write in:

Is product repackaged? No

Is product sold by manufacturer's exclusive distributor? Yes

Has FDA granted waiver/exception/exemption for product? No

If yes, attach documentation from FDA.

GLN: 0860000397957

GCP:

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces |
|----------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
| | | Depth | Width | Height | | |
| Item/Each: | 0.11 | 1.76 | 1.76 | 2.98 | 9.25 | 1 |
| Box/ Carton/ Bundle/ Inner Pack: | | | | | | |
| Case: | 3.2 | 11 | 7.5 | 3.2 | 264.00 | 24 |
| Pallet: | | | | | | |

GTIN AND HIBCC PRODUCT INFORMATION

| Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|-------------------------|----------------------|-------------------------------------|----------------------|
| <input checked="" type="checkbox"/> Item/Each | <input type="text"/> 1 | <input type="text"/> | <input type="text"/> 00331722953016 | <input type="text"/> |
| <input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input checked="" type="checkbox"/> Case | <input type="text"/> 24 | <input type="text"/> | <input type="text"/> 10331722953013 | <input type="text"/> |
| <input type="checkbox"/> Pallet | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

COST INFORMATION

Regular Cost
Invoice Cost (WAC) (\$) \$74.75
 As of date: 9/1/2021

WHOLESALE USE ONLY:
Vendor #:
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.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 Is the product a CA Prop 65 carcinogen? No
 Is the product a CA Prop 65 reproductive toxicant? No
 Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard? No

d. Does this product require special clean-up instructions?
 (If yes, attach SDS with special instructions.) No

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT?
 (if yes, answer a-e below and provide SDS) No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard? No

Is this product regulated for shipment by IATA?
 (if yes, answer a-e below and provide SDS) No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction: No

Passenger
 Cargo
 Passenger & Cargo

Is this a reportable quantity? No
 RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 No (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? Yes No Controlled Substance Code

Controlled by State(s)? Yes No Listed Chemical (List I or II) Yes No

ARCOS Reportable? Yes No If yes, indicate which:

Schedule No. 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 Yes No

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

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.

| SDS Hazard Classification | |
|---|---|
| <input checked="" type="checkbox"/> Organic | <input type="checkbox"/> Corrosive |
| <input type="checkbox"/> Inorganic | <input type="checkbox"/> Oxidizer |
| <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Contact Hazard |
| Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> | <input type="checkbox"/> No |
| NFPA Storage Level: <input type="text"/> | |
| Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/> | <input type="checkbox"/> No |

| Hazardous Waste Identification | |
|--|--|
| EPA Hazardous Waste Code: <input type="text"/> | Waste Characteristics <input type="text"/> |

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? No

Website URL:

Med Guide Required No

Limited Distribution Requirement No

Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name:

Site Enrollment Number assigned by Supplier:

Comments

Registry: No

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes No

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? Yes No

If so, which states? Other requirements? Comments?

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



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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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/> | Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/> | Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/> |
| Class of Trade Restriction: | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/> | |
| Other Data Information Required to Process PO: | Return Instructions |
| Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/> | Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/> |
| Miscellaneous Notes: | |
| | ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/> |