



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

Version 2021 Introduction Type:   Final Version Date:

**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):** 215523  
**Medical Device Class, if applicable:**   
**DUNS:** 82-677-4775  
**Proprietary Name (If Applicable) and Established Name:** Dexmethylphenidate HCl ER 40mg 100ct  
**Selling Unit NDC:** 31722-236-01 **Unit of Use NDC:**  **UPC:** 331722236010  
**UDI**  **CVX Code:**  **MVX Code:**   
**Description:** Oral solid capsule, capsule shaped, yellow/white, M40 and AC  
**Active Ingredient(s):** Dexmethylphenidate Hydrochloride  
**URL for Additional Product Information:**   
**Address:** 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 **Address 2:**   
**City:** Piscataway **State:** NJ **Zip:** 08854  
**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788  
**Product Therapeutic Classification:**

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:   
 Other Temperature Range Requirement (write in):   
 Notes:   
 Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?   
**b. Contact for temperature excursion questions:**  
**Name:**   
**Number:**   
**Group E-mail:**   
**c. Special regulations for product in any states?**   
 Special returns requirements for this product?   
**d. Store product (unit of sale) upright?**   
**e. Shelf life:**   
 Protect product (unit of sale) from light?   
 Initial shelf life at launch (if different):  Months  
 Months  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Is the Product... Orphan Drug Status	<input type="text" value="Direct-Ship Only"/> <input type="text" value="Neither"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	FDA Approval Status	<input type="text" value="100ct"/>
co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="text" value="No"/> <input type="text" value="Yes"/> <input type="text" value="Yes"/> <input type="text" value="No"/> <input type="text" value="No"/>	Allergens Present	Strength: <input type="text" value="40mg"/> Dosage Form: <input type="text" value="Oral Solid - Capsule"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:	<input type="text" value="No"/> <input type="text"/>	Country of Origin <input type="text" value="USA"/> Is this product covered under the Trade Agreements Act (TAA)?	Product Shape: <input type="text" value="Capsule Shaped"/> Product Color: <input type="text" value="Yellow/White"/> Product Imprint: <input type="text" value="M40 and AC"/>

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 bottle of 100 capsules"/>
<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 Power Multi	
<input type="checkbox"/> Other: Write In	

Minimum order quantity?   
 If Yes, how many of which package type?  
 Each  
 Inner/ Carton/ Pack  
 Case

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:   Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?:

**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?   
 Is product exempt from DSCSA?   
 If yes, select exemption:   
 Other exemption - Write in:   
 Is product repackaged?   
 Is product sold by manufacturer's exclusive distributor?   
 Has FDA granted waiver/exception/exemption for product?   
 If yes, attach documentation from FDA.   
**GLN:** 0331722000000  
**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:	0.24		2.38	4.239		1
Box/Carton/Bundle/ Inner Pack:						
Case:	3	16	10.75	5.5		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	1		00331722236010	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722236017	
<input type="checkbox"/> Pallet				

**COST INFORMATION** **WHOLESALE USE ONLY:**

**Regular Cost**   
**Invoice Cost (WAC) (\$)**   
 As of date:   
**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:

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):	
a. Cytotoxic?	<input type="checkbox"/> No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/> No
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/> No
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/> No
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/> No
c. Contact Hazard?	<input type="checkbox"/> No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No
e. Does the product contain DEHP?	<input type="checkbox"/> No
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	<input type="checkbox"/> No
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	<input type="checkbox"/> No
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
Is the product restricted for air shipment? If so, indicate restriction:	<input type="checkbox"/> No
<input type="checkbox"/> Passenger	
<input type="checkbox"/> Cargo	
<input type="checkbox"/> Passenger & Cargo	
Is this a reportable quantity? <input type="checkbox"/>	
RQ Threshold: <input type="text"/>	
Is this a marine pollutant? <input type="checkbox"/> No	
Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> (if yes, identify method below)	
<input type="checkbox"/> Limited Quantity	
<input type="checkbox"/> Consumer Commodity, ORM-D	
<input type="checkbox"/> Small Quantity (49 CFR 173.4)	
<input type="checkbox"/> Special Permit; DOT-SP	
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/>	
ADD'L STORAGE INFORMATION	
Is the Product...	
Controlled Substance?	<input type="checkbox"/> Yes      Controlled Substance Code <input type="text" value="1724"/>
Controlled by State(s)?	<input type="checkbox"/> No      Listed Chemical (List I or II) <input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> If yes, indicate which: <input type="text"/>
Schedule No.	<input type="text" value="2"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	<input type="checkbox"/> Yes
Restricted to retail pharmacy only:	<input type="checkbox"/> No
Restricted to hospital, clinics, and physician offices only:	<input type="checkbox"/> No
Restricted from US territories? (explain in comments)	<input type="checkbox"/> No
Comments:	<input type="text"/>
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"/>
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug? If yes, indicate which:	<input type="checkbox"/> No <input type="text"/>
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?	<input type="checkbox"/> No
If Yes, is it managed with a pharmacy registry? Website URL:	<input type="text"/>
Med Guide Required	<input type="checkbox"/>
Limited Distribution Requirement	<input type="checkbox"/>
Comments / Details: (For example, iPledge program?)	<input type="text"/>
<b>REMS:</b>	<input type="checkbox"/> No
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="checkbox"/>
Wholesale distributor support:	<input type="checkbox"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text"/>
<b>Registry:</b>	<input type="checkbox"/> No
Registry Program Contact Name:	<input type="text"/>
Comments	<input type="text"/>
Phone:	<input type="text"/>
RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<input type="text" value="1-866-827-3647"/>
Is product returnable for credit:	<input type="checkbox"/> Yes
URL/Link to returns policy:	<input type="text" value="contact - customerservice@camberpharma.com"/>
Special regulations or returns requirements for this product in certain states?	<input type="checkbox"/> No
If so, which states? Other requirements? Comments?	<input type="text"/>
MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input type="text"/>	



# 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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> 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"/>	<b>Purchase order daily receipt cut off time by supplier</b> 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"/>	<b>Overnight receipt available:</b> <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 <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <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:	
	<b>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>