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

**Version 2021** | **Introduction Type:** New Item | x Final Version | **Date:** 6/4/2024

## PRODUCT INFORMATION

**Company Name:** Camber Pharmaceuticals, Inc. | **Application:** ANDA
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 214959
**Medical Device Class, if applicable:**
**DUNS:** 11-856-3719
**Proprietary Name (If Applicable) and Established Name:** Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) 10 mg
**Selling Unit NDC:** 31722-186-01 | **Unit of Use NDC:** | **UPC:** 331722186018
**UDI:** | **CVX Code:** | **MVX Code:**
**Description:** Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) 10 mg
**Active Ingredient(s):** Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, USP, and amphetamine sulfate, 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

## ADDITIONAL PRODUCT INFORMATION

**The product is?**
- **a legend device?** No
- **if yes, enter class #**
- **a product kit?** No
- **if yes, list NDCs of component parts**
- **reverse numbered?** No
- **co-licensed?** No
- **latex-free?** Yes
- **preservative-free?** Yes
- **correctional institution block?** No
- **opioid?** No
- **Cannabinoid?** No

If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose, indicate NDC here:

**Is the Product…** Direct-Ship Only
**Is the Product…** Neither
**Orphan Drug Status**
**FDA Approval Status**
**Allergens Present:** Dye, Corn, Alcohol, Animal, Sugar
Country of Origin: USA
Is this product covered under the Trade Agreements Act (TAA)? Yes

## PRODUCT DESCRIPTION INFORMATION

**Size:** 100 ct
**Strength:** 10 mg
**Dosage Form:** Extended-release, hard gelatin capsule
**Product Shape:** Capsule
**Product Color:** Blue opaque cap and blue transparent body
**Product Imprint:** Imprinted with '10 mg' on cap and 'T' on body in black ink

## FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable
**I. Orange Book Rating:** AB1
**II. Generic Equivalent to What Brand?:** Adderall XR

## 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**

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|
| x | Item/Each | 1 | | 00331722186018 | |
| | Box/Carton/Bundle/Inner Pack | | | | |
| x | Case | 24 | | 10331722186015 | |
| | Pallet | | | | |

## SPECIAL HANDLING AND STORAGE REQUIREMENTS*

**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): Excursions permitted to 15° to 30°C (59° to 86°F)
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

## ORDER INFORMATION

**Unit of Sale**

| | |
|---|---|
| x | Bottle |
| | Box/Carton |
| | Ampule |
| | Glass |
| | Tube |
| | Vial Liquid Sgl |
| | Vial Liquid Multi |
| | Vial Powder Sgl |
| | Vial Powder Multi |
| | Other: Write In |

**What is the NDC selling unit?** 1 Bottle of 100 Capsules
(Write-in, e.g. 1 Box of 10 Vials)
**Minimum order quantity?** Yes
**If Yes, how many of which package type?**
24 Each
Inner/Carton/Pack
Case

## PHARMACY ORDER / BILL UNIT

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

**Rx billing unit to pharmacy:**
Each
Gram
Milliliter

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| **Item/Each:** | 0.09 | 1.88 | 1.88 | 3.23 | 11.35 | 1 |
| **Box/Carton/Bundle/ Inner Pack:** | | | | | | |
| **Case:** | 2.6 | 12.3 | 8.3 | 3.8 | 387.94 | 24 |
| **Pallet:** | | | | | | |

## COST INFORMATION

**Regular Cost**
**Invoice Cost (WAC) ($)** $70.00
As of date: 10/25/2021

## WHOLESALER 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:**

# 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 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? | |
| 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? | |
| 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#

### SDS Hazard Classification

| | | | |
|---|---|---|---|
| x | Organic | | Corrosive |
| | Inorganic | | Oxidizer |
| | Steroid/Androgen | | Contact Hazard |

| | |
|---|---|
| Does the product have an Aerosol class? If yes, identify NFPA Storage Level: | No |
| NFPA Storage Level: | |
| Is the product a NIOSH hazardous drug? | No |
| If yes, indicate which: | |

### Hazardous Waste Identification

| | | | |
|---|---|---|---|
| EPA Hazardous Waste Code: | | Waste Characteristics | |

## REMS or REGISTRY RESTRICTIONS

| | | | |
|---|---|---|---|
| Is there a REMS on this product? | No | | |
| If Yes, is it managed with a pharmacy registry? | | | |
| Website URL: | | | |
| Med Guide Required | No | | |
| Limited Distribution Requirement | | | |
| Comments / Details: (For example, iPledge program?) | | | |
| **REMS:** | No | | |
| REMS Program Manager Name: | | Phone: | |
| Supplier Manages REMS registry exclusively: | | | |
| Wholesale distributor support: | | | |
| Provider Name: | | DEA #: | |
| Site Enrollment Number assigned by Supplier: | | NCPDP#: | |
| | | NPI #: | |
| Comments | | | |
| **Registry:** | No | | |
| Registry Program Contact Name: | | Phone: | |
| Comments | | | |

## ADD'L STORAGE INFORMATION

Is the Product…

| | | | |
|---|---|---|---|
| Controlled Substance? | Yes | Controlled Substance Code | 1100 |
| Controlled by State(s)? | Yes | Listed Chemical (List I or II) | No |
| ARCOS Reportable? | Yes | If yes, indicate which: | |
| Schedule No. | 2 | 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 |
| Restricted to retail pharmacy only: | No |
| Restricted to hospital, clinics, and physician offices only: | No |
| Restricted from US territories? (explain in comments) | No |
| 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.

# 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

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

## Standard Order Receipt and Processing

**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?