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

**Version 2021** | **Introduction Type:** Post Launch Change | x Final Version | **Date:** 11/19/2024

## PRODUCT INFORMATION

| | |
|---|---|
| **Company Name:** | Camber Pharmaceuticals, Inc. |
| **Application:** | ANDA |
| **Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** | 202682 |
| **Medical Device Class, if applicable:** | |
| **DUNS:** | 11-856-3719 |
| **Proprietary Name (If Applicable) and Established Name:** | Atomoxetine Hydrochloride Capsules, USP 80 mg |
| **Selling Unit NDC:** | 31722-719-30 |
| **Unit of Use NDC:** | 31722-719-30 |
| **UPC:** | 331722719308 |
| **UDI** | |
| **CVX Code:** | |
| **MVX Code:** | |
| **Description:** | Atomoxetine Hydrochloride Capsules, USP 80 mg |
| **Active Ingredient(s):** | Atomoxetine 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:** | Selective norepinephrine reuptake inhibitor (SNRI) |

## 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…** | Unit of Use |
| **Orphan Drug Status** | |
| **FDA Approval Status** | |
| **Allergens Present** | Animal Products |
| Country of Origin | India |
| Is this product covered under the Trade Agreements Act (TAA)? | No |

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| **Size:** | 30 ct |
| **Strength:** | 80 mg |
| **Dosage Form:** | Hard gelatin capsule |
| **Product Shape:** | Capsule |
| **Product Color:** | Brown opaque cap and white opaque body |
| **Product Imprint:** | Imprinted with 'I' on cap and '110' on body |

## 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?:** | Strattera |

## 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:** | 0331722498975 |
| **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 | | 00331722719308 | 00331722719308 |
| | Box/Carton/Bundle/Inner Pack | | | | |
| x | Case | 24 | | 20331722719302 | |
| | 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) | |
| 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?** | No |
| Special returns requirements for this product? | No |
| **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 30 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:** | 0.08 | 1.55 | 1.55 | 2.55 | 6.13 | 1 |
| **Box/Carton/Bundle/ Inner Pack:** | | | | | | |
| **Case:** | 2.3 | 9.75 | 6.75 | 4 | 263.25 | 24 |
| **Pallet:** | | | | | | |

## COST INFORMATION

| | |
|---|---|
| **Regular Cost** | |
| **Invoice Cost (WAC) ($)** | $57.38 |
| As of date: | 12/1/2024 |

## 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)

**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? | 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
- [ ] Inorganic
- [ ] Steroid/Androgen
- [ ] Corrosive
- [ ] Oxidizer
- [ ] 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? | No | Controlled Substance Code | |
| Controlled by State(s)? | No | Listed Chemical (List I or II) | No |
| ARCOS Reportable? | 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 |
| 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? | No |

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

# 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?