



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

Version 2024

Introduction Type: Post Launch Change

Final Version

Date: 6/13/2024

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Camber Pharmaceuticals, Inc. |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 214790 |
| Application: | ANDA |
| Medical Device Class, if applicable: | |
| DUNS: | 11-856-3719 |
| Proprietary Name (If Applicable) and Established Name: | Sertraline Hydrochloride Tablets, USP 100 mg (base) |
| Selling Unit NDC: | 31722-147-05 |
| Unit of Use NDC: | |
| UPC: | 331722147057 |
| CVX Code: | |
| MXV Code: | |
| Description: | Sertraline Hydrochloride Tablets, USP 100 mg (base) |
| Active Ingredient(s): | Sertraline hydrochloride, USP |
| URL for Additional Product Information: | www.camberpharma.com |
| Address: | 800 Centennial Ave, Suite 1 |
| City: | Piscataway |
| Key Contact: | Customer Service |
| Phone Number: | 1-866-827-3647 |
| Product Therapeutic Classification: | Selective serotonin reuptake inhibitor (SSRI) |

| 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? | <input type="checkbox"/> No |
| Is this product to be shipped to customers on dry ice? | <input type="checkbox"/> 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? | |
| Special returns requirements for this product? | <input type="checkbox"/> No |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="checkbox"/> No |
| e. Shelf life: | |
| Initial shelf life at launch (if different): | <input type="text" value="24"/> Months |

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|------------------------------|---|--|
| The product is? | | Is the Product... Direct-Ship Only | |
| a legend device? | <input type="checkbox"/> No | Is the Product... Neither | |
| if yes, enter class # | | Orphan Drug Status | |
| a product kit? | <input type="checkbox"/> No | FDA Approval Status | |
| if yes, list NDCs of component parts | | Allergens Present | Corn, Alcohol, Sugar |
| reverse numbered? | <input type="checkbox"/> No | Country of Origin | USA |
| co-licensed? | <input type="checkbox"/> No | Is this product covered under the Trade Agreements Act (TAA)? | <input type="checkbox"/> Yes |
| latex-free? | <input type="checkbox"/> Yes | | |
| preservative-free? | <input type="checkbox"/> Yes | | |
| correctional institution block? | <input type="checkbox"/> No | | |
| opioid? | <input type="checkbox"/> No | | |
| 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: | | | |
| | | Size: | 500 ct |
| | | Strength: | 100 mg |
| | | Dosage Form: | Film coated tablet |
| | | Product Shape: | Modified capsule |
| | | Product Color: | Light yellow |
| | | Product Imprint: | One side debossed with 'T' and '100' with functional score line in between and plain on the other side |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 1 Bottle of 500 Tablets |
| <input type="checkbox"/> Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | |
| <input type="checkbox"/> Glass | Minimum order quantity? <input type="checkbox"/> Yes |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Powder Sgl | <input type="text" value="24"/> Each |
| <input type="checkbox"/> Vial Powder Multi | <input type="text"/> Inner/Carton/Pack |
| <input type="checkbox"/> Other: Write In | <input type="text"/> Case |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | AB |
| II. Generic Equivalent to What Brand?: | Zoloft |
| <input type="checkbox"/> Authorized Generic | *If Authorized Generic, other section fields are not applicable |

| PHARMACY ORDER / BILL UNIT | |
|-----------------------------|-------------------------------------|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| <input type="text"/> | <input type="checkbox"/> Each |
| (Write-in, e.g. 1 Vial) | <input type="checkbox"/> Gram |
| HCPCS J-Code: | <input type="checkbox"/> Milliliter |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|------------------------------|
| Does supplier meet DSCSA definition of manufacturer? | <input type="checkbox"/> Yes |
| Is product exempt from DSCSA? | <input type="checkbox"/> No |
| If yes, select exemption: | |
| Other exemption - Write in: | |
| Is product repackaged? | <input type="checkbox"/> No |
| Is product sold by manufacturer's exclusive distributor? | <input type="checkbox"/> Yes |
| Has FDA granted waiver/exception/exemption for product? | <input type="checkbox"/> No |
| If yes, attach documentation from FDA. | |
| GLN: | 0331722498975 |
| GCP: | |
| If yes, was original product purchased direct from mfr? | <input type="checkbox"/> |
| Provide source manufacturer for repackaged product | |

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces |
| | | Depth | Width | Height | | |
| Box/Carton/Bundle/Inner Pack: | 0.36 | 2.36 | 2.36 | 4.3 | 23.95 | 1 |
| Case: | 9.3 | 14.5 | 10.25 | 5 | 743.13 | 24 |
| Pallet: | | | | | | |

| GTIN AND HIBCC PRODUCT INFORMATION | | | | |
|--|---------------|-------------------|-------|----------------|
| Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 |
| <input checked="" type="checkbox"/> Item/Each | N | 1 | | 00331722147057 |
| <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | N | 24 | | 10331722147054 |
| <input type="checkbox"/> Pallet | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------|-----------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$42.75 | Whsl. Code #: | |
| As of date: | 7/23/2021 | 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#

SDS Hazard Classification

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:

