



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

| PRODUCT INFORMATION | |
|---|---|
| Company Name: | Camber Pharmaceuticals |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 214790 |
| Application: | ANDA |
| DUNS: | 826774775 |
| Proprietary Name (If Applicable) and Established Name: | Sertraline Hydrochloride Tablet 100mg 30ct |
| Selling Unit NDC: | 31722-147-30 |
| Individual Unit NDC: | |
| UPC: | |
| UDI | |
| CVX Code: | |
| MXV Code: | |
| Description: | Oral Solid Tablet, Modified Capsule, Light Yellow, Upper: Embossed with "T" Bisect "100" Lower: Plain |
| Active Ingredient(s): | Sertraline Hydrochloride |
| URL for Additional Product Information: | www.camberpharma.com |
| Address: | 1031 Centennial Avenue |
| City: | Piscataway |
| Key Contact: | Customer Service |
| Phone Number: | 732-529-0430 |
| Product Therapeutic Classification: | |
| State: | NJ |
| Address 2: | |
| Zip: | 08854 |
| Email: | customerservice@camberpharma.com |
| Fax: | 732-562-8788 |

| 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) | |
| Is this product to be shipped to customers on ice? | <input type="checkbox"/> |
| Is this product to be shipped to customers on dry ice? | <input type="checkbox"/> |
| 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"/> |
| d. Store product (unit of sale) upright? | <input type="checkbox"/> |
| Protect product (unit of sale) from light? | <input type="checkbox"/> |
| e. Shelf life: | |
| Initial shelf life at launch (if different): | <input type="text"/> Months |

| ADDITIONAL PRODUCT INFORMATION | |
|---|-----------------------------|
| Is the Product... a legend device? | <input type="checkbox"/> No |
| reverse numbered? | <input type="checkbox"/> No |
| co-licensed? | <input type="checkbox"/> No |
| Is the Product... Direct-SHIP Only | <input type="checkbox"/> |
| Is the Product... Neither | <input type="checkbox"/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="checkbox"/> No |
| If Unit Dose NDC, indicate NDC here: | <input type="text"/> |
| Country of Origin | USA |
| Is this product covered under the Trade Agreements Act (TAA)? | <input type="checkbox"/> |

| PRODUCT DESCRIPTION INFORMATION | |
|---------------------------------|--|
| Size: | 30 |
| Strength: | 100mg |
| Dosage Form: | Oral Solid - Tablet |
| Product Shape: | Modified Capsule |
| Product Color: | Light Yellow |
| Product Imprint: | Upper: Embossed with "T Bisect 100" Lower: Plain |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 1 bottle of 30 count |
| <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 | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Liquid Multi | <input type="text"/> 24 Each |
| <input type="checkbox"/> Vial Powder Sgl | <input type="text"/> Inner/Carton/Pack |
| <input type="checkbox"/> Vial Power Multi | <input type="text"/> Case |
| <input type="checkbox"/> Other: Write In | |

| 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 |
| | <input type="checkbox"/> Milliliter |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|---|
| Does supplier meet DSCSA definition of manufacturer? | <input checked="" 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"/> No |
| Has FDA granted waiver/exception/exemption for product? | <input type="checkbox"/> No |
| GLN: | 0331722000000 |
| If Yes, was original product purchased direct from mfr? | <input type="checkbox"/> |
| If yes, attach documentation from FDA. | |

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width | | |
| Box/Carton/Bundle/Inner Pack: | 0.049 | | 2.694 | 1.52 | | 1 |
| Case: | 1.6 | 9.8 | 3 | 6.5 | | 24 |
| Pallet: | | | | | | |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|-------------------------------------|------------------------------|------|-------------------------------------|----------|----------------|--------------------------|
| Serialized? | Level | Item | Saleable Unit | Quantity | GTIN-14 | Items aggregated? |
| | | | | | | |
| <input checked="" type="checkbox"/> | Box/Carton/Bundle/Inner Pack | | <input checked="" type="checkbox"/> | 1 | 00331722147309 | <input type="checkbox"/> |
| <input type="checkbox"/> | Case | | <input checked="" type="checkbox"/> | 24 | 10331722147306 | <input type="checkbox"/> |
| <input checked="" type="checkbox"/> | Pallet | | <input checked="" type="checkbox"/> | | | <input type="checkbox"/> |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------------------|--------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$2.85 | Whsl. Code #: | |
| Federal Excise Tax Per Unit of Sale | | Fineline Code: | |
| As of date: | | | |

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 or 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:

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?
 (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? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No
 If yes, indicate which:

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:

SDS Hazard Classification

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?
 If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
 If Yes, is it managed with a pharmacy registry?
 Website URL:

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

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:
 Provider Name:

Site Enrollment Number assigned by Supplier: DEA #:

PCPDP #:

NPI #:

Comments

Registry: No
 Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes

URL/Link to returns policy:

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:

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 |
|--|--|
| <p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/> Eastern</p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> | <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/> Eastern</p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction: | Return Instructions |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" type="text"/></p> |
| Other Data Information Required to Process PO: | ADDITIONAL INFORMATION |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> |
| Miscellaneous Notes: | |
| <input style="width: 100%; height: 100px;" type="text"/> | |