



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): | 216800 | | |
| Medical Device Class, if applicable: | | | |
| DUNS: | 11-856-3719 | | |
| Proprietary Name (If Applicable) and Established Name: | Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 200 mg | | |
| Selling Unit NDC: | 31722-068-01 | Unit of Use NDC: | |
| UDI | | UPC: | 331722068017 |
| | | CVX Code: | |
| | | MXV Code: | |
| Description: | Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 200 mg | | |
| Active Ingredient(s): | Bupropion hydrochloride, USP | | |
| URL for Additional Product Information: | www.camberpharma.com | | |
| Address: | 800 Centennial Ave, Suite 1 | Address 2: | |
| City: | Piscataway | State: | NJ |
| Key Contact: | Customer Service | Zip: | 08854 |
| Phone Number: | 1-866-827-3647 | Email: | customerservice@camberpharma.com |
| Product Therapeutic Classification: | Aminoketone antidepressant (NDRI) | Fax: | 732-562-8788 |

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

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|----------------------------------|---|---|
| The product is a legend device? if yes, enter class # | <input type="text" value="No"/> | Is the Product... Direct-Ship Only | <input type="text"/> |
| a product kit? if yes, list NDCs of component parts reverse numbered? | <input type="text" value="No"/> | Is the Product... Orphan Drug Status | <input type="text" value="Neither"/> |
| co-licensed? | <input type="text" value="No"/> | FDA Approval Status | <input type="text"/> |
| latex-free? | <input type="text" value="No"/> | Allergens Present | <input type="text"/> |
| preservative-free? | <input type="text" value="Yes"/> | Dye | <input type="text"/> |
| correctional institution block? | <input type="text" value="No"/> | Country of Origin | <input type="text" value="India"/> |
| opioid? | <input type="text" value="No"/> | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/> |
| Cannabinoid? | <input type="text" value="No"/> | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text"/> | | |
| If Unit Dose, indicate NDC here: | <input type="text"/> | | |
| | | Size: | <input type="text" value="100 ct"/> |
| | | Strength: | <input type="text" value="200 mg"/> |
| | | Dosage Form: | <input type="text" value="Film coated tablet"/> |
| | | Product Shape: | <input type="text" value="Round, biconvex, bevel edged"/> |
| | | Product Color: | <input type="text" value="Yellow"/> |
| | | Product Imprint: | <input type="text" value="Imprinted with 'V1 50' on one side and plain on other side"/> |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 Bottle of 100 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="text"/> |
| <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" value="24"/> Each |
| <input type="checkbox"/> Vial Powder Sgl | <input type="text"/> |
| <input type="checkbox"/> Vial Powder Multi | Inner/ Carton/ Pack |
| <input type="checkbox"/> Other: Write In | Case |

| FOR GENERIC DRUG PRODUCTS | |
|--|--|
| I. Orange Book Rating: | <input type="text" value="AB1"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable |
| II. Generic Equivalent to What Brand?: | <input type="text" value="Wellbutrin SR"/> |

| PHARMACY ORDER / BILL UNIT | |
|--|---|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| <input type="text" value="100 Tablets"/> | <input type="text" value="Each"/> |
| (Write-in, e.g. 1 Vial) | <input type="text" value="Gram"/> |
| | <input type="text" value="Milliliter"/> |

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

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|-------|-------|--------|---------------|-------------------|
| Item/Each: | Weight Lbs. | Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
| Box/Carton/Bundle/Inner Pack: | 0.21 | 2.18 | 2.18 | 3.9 | 18.53 | 1 |
| Case: | 6.85 | 13.63 | 9.5 | 5 | 647.19 | 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 | | 00331722068017 | |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | 24 | | 30331722068018 | |
| <input type="checkbox"/> Pallet | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------|---|---------------------|----------------------|
| Regular Cost | <input type="text"/> | Vendor #: | <input type="text"/> |
| Invoice Cost (WAC) (\$) | <input type="text" value="\$26.00"/> | Whsl. Code #: | <input type="text"/> |
| As of date: | <input type="text" value="10/16/2023"/> | Fineline Code: | <input type="text"/> |

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? 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:



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