



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

Version 2021

Introduction Type: New Item

Final Version

Date: 11/6/2023

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) 100 mg Selling Unit NDC: 31722-066-60 Unit of Use NDC: 31722-066-60 UPC: 331722066600 UDI _____ CVX Code: _____ MXV Code: _____ Description: Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 100 mg Active Ingredient(s): Bupropion Hydrochloride URL for Additional Product Information: www.camberpharma.com Address: 1031 Centennial Ave (and) 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: Aminoketone Antidepressant (NDRI)		a. Temperature – Indicate the USP temperature range for this product. Temperature Range <input type="text" value="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? <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? <input type="checkbox"/> No Protect product (unit of sale) from light? <input type="checkbox"/> No e. Shelf life: <input type="checkbox"/> 24 Months Initial shelf life at launch (if different): _____ Months				
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION				
The product is? a legend device? <input type="checkbox"/> No if yes, enter class # _____ a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? _____ co-licensed? <input type="checkbox"/> No 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: _____		Is the Product... <input type="checkbox"/> Direct-Ship Only Is the Product... <input type="checkbox"/> Unit of Use Orphan Drug Status _____ FDA Approval Status _____ Allergens Present <input type="checkbox"/> Dye Country of Origin <input type="text" value="India"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No				
		Size: 60 ct Strength: 100 mg Dosage Form: Film coated tablet Product Shape: Round, biconvex, bevel edged Product Color: Red Product Imprint: "V1 48" on one side and plain on other side				
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"/>						
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: 0331722000000 GCP: _____ If yes, was original product purchased direct from mfr? <input type="checkbox"/> _____ Provide source manufacturer for repackaged product _____				
GTIN AND HIBCC PRODUCT INFORMATION						
Saleable Unit of Measure <input checked="" type="checkbox"/> Item/Each <input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack <input checked="" type="checkbox"/> Case <input type="checkbox"/> Pallet		Saleable Quantity <input type="text" value="1"/> <input type="text" value="24"/> <input type="text" value=""/>				
		HIBCC _____ <input type="text" value=""/>				
		GTIN-14 00331722066600 <input type="text" value="30331722066601"/>				
		Unit of Use GTIN-14 00331722066600				
COST INFORMATION		WHOLESALE USE ONLY:				
Regular Cost _____ Invoice Cost (WAC) (\$) <input type="text" value="\$12.00"/> As of date: 10/16/2023		Vendor #: _____ Whsl. Code #: _____ Fineline Code: _____				
ORDER INFORMATION						
Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/ Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In _____		What is the NDC selling unit? <input type="text" value="1 Bottle of 60 Tablets"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? <input type="text" value="24"/> Each <input type="text" value=""/> Inner/ Carton/ Pack <input type="text" value=""/> Case				
PHARMACY ORDER / BILL UNIT						
Rec. sell unit to customer? _____ (Write-in, e.g. 1 Vial)		Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter				
ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
	Depth	Width	Height			
Item/Each:	0.16	1.85	1.85	3.23	11.05	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	4.4	11.69	8	4.5	420.84	24
Pallet:						

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

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)

- 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)

- 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 No
- 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#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- Restricted to retail pharmacy only: No Yes
- Restricted to hospital, clinics, and physician offices only: No Yes
- Restricted from US territories? (explain in comments) No Yes

Comments:

SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

Is the product a NIOSH hazardous drug? If yes, indicate which: No

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

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

Med Guide Required No Yes
Limited Distribution Requirement No Yes
Comments / Details: (For example, iPledge program?)

REMS: No Yes
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: No Yes
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: No Yes

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No Yes

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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> <ul style="list-style-type: none"> 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"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></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 type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <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: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>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:	
<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 type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<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>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 type="text"/></p>
Miscellaneous Notes:	
<p><input type="text"/></p>	
	ADDITIONAL INFORMATION
	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>