

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

						Introduction Type:	New Item		x Final Version			Date:	6/6/	2024
			PRODUCT INFORMA	ATION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperatu	ure - Indicate the USP temp	erature range for th	nis product.			
Application Number for NDA/AN			ce):	216	6800			a. romporate	Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica			,-						·			`		
DUNS:	11-856-3719							_	Other Temperature Range	Requirement	Excursions p	ermitted bet	veen 15° and	130°C (59°
Proprietary Name (If Applicable)		me: Bupro	pion Hydrochloride Extende	d-Release Tablet	ts. USP (SR) 10	10 ma		Т	(write in)	toquiromont	and 86°F)	ommitod bot		. 00 0 00
Selling Unit NDC:	31722-066-60	ше.	Unit of Use NDC		31722-066-60		722066600	†	Notes		,			
UDI			CVX Code:			MVX Code:		†						
December 1	Dunganian Uludran	blasida Eutaadad Da	lease Tablets, USP (SR) 10	20				Ť	la thia anadust ta ha ahisaa	d toto	-2		No	1
Description:	Bupropion Hydroc	nionae Extenaea-Re	lease Tablets, USP (SR) It	ou mg					Is this product to be shippe Is this product to be shippe				No	-
Active Ingredient(s):		Bupropion hydrochl	lorido LICD					+	is this product to be shippe	a to customers on a	ry ice r		INO	
Active ingredient(s).		Bupropion nydrocni	lolide, OSF					h Contact fo	or temperature excursion qu	estions:				
URL for Additional Product Inforr	mation.	www.camberpharma	a com					b. Contact to	Name:	estions.	Soma Raju			
Address:	800 Centennial Av		<u> </u>			Address 2:		+	Number:		732-529-042	3		
City:	Piscataway	-,			State:		: 08854		Group E-mail:		somaraju@h		n	
Key Contact:	Customer Service				Email:	customerservice@cam	berpharma.com						_	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	·	c. Special re	gulations for product in any	states?			No	1
Product Therapeutic Classification	on:	Aminoketone antide	epressant (NDRI)					-	Special returns requiremen				No	
			. , ,		J				.,					_
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nlv			11 ·	Protect product (unit of sa	ale) from light?			No	i
a legend device?		No	Is the Product	Unit of Use	,		60 ct	e. Shelf life:	r roteet product (unit or si	iic) ii oiii iigiit i			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:	00 01	c. onen me.	Initial shelf life at launch (if different):			2-7	Months
a product kit?		No	Orphan Drug Otatus				100 mg		initial shell life at launen	ii dinerenty.				Months
if yes, list NDCs of		,,,,	FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts						1	Film coated tablet							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 6) Tablets		
latex-free?		Yes	_	Dye		Product Shape:	Round, biconvex, bevel		Box/Carton		(Write-in, e.	g. 1 Box of 1) Vials)	
preservative-free?		Yes		Dye		Froduct Snape.	edged		Ampule					
correctional institution block?		No				Product Color:	Red		Glass		Minimum or	der quantity	?	Yes
opioid?		No				r roduct color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Imprinted with 'V1 48' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for						side and plain on other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act	(TAA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
						1						Ouoo		
			FOR GENERIC DRUG P	RODUCTS								ouoo		
			FOR GENERIC DRUG PR	RODUCTS		havinad Canaria 116 A	uthorized Conorio other			IARMACY ORDER				
			FOR GENERIC DRUG PI	RODUCTS	Aut		uthorized Generic, other		PF	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB1		FOR GENERIC DRUG PR	RODUCTS	Aut		uthorized Generic, other ion fields are not applicable	Rec. sell unit		IARMACY ORDER		nit to pharm	acy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Wellbutrin SR	FOR GENERIC DRUG P	RODUCTS	Aut				Pit to customer?	IARMACY ORDER	/ BILL UNIT	nit to pharma	асу:	
					<u></u>			Rec. sell unit	Pit to customer?	IARMACY ORDER	/ BILL UNIT	nit to pharma Each Gram	acy:	
			FOR GENERIC DRUG PI		<u></u>				Pit to customer?	IARMACY ORDER	/ BILL UNIT	nit to pharma	acy:	
	and?:	DRUG SUPPL		(DSCSA) INFOR	<u></u>				PH t to customer? j. 1 Vial)	IARMACY ORDER	/ BILL UNIT Rx billing u	nit to pharma Each Gram Milliliter	асу:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	MATION	sect			PH t to customer? j. 1 Vial)		/ BILL UNIT Rx billing u	nit to pharma Each Gram Milliliter	асу:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	LY CHAIN SECURITY ACT Yes	(DSCSA) INFOR	MATION	sect			PH t to customer? [1.1 Vial)	I AND PACKING IN	/ BILL UNIT Rx billing u	nit to pharm Each Gram Milliliter	acy:	Saleable #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPPL	LY CHAIN SECURITY ACT Yes	(DSCSA) INFOR	MATION GLN:	sect			PH t to customer? j. 1 Vial)	I AND PACKING IN	/ BILL UNIT Rx billing un	nit to pharma Each Gram Milliliter		Saleable #
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Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	and?: ition of manufactur s exclusive distribu	DRUG SUPPL	Yes No No Yes	(DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	0331722498975 Iginal product purchase	ion fields are not applicable	(Write-in, e.g	pt to customer? p. 1 Vial) Weight Lbs. 0.16	I AND PACKING IN Dimensi Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width	nit to pharm Each Gram Milliliter	Volume (Cube)	Pieces
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption: Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptic If yes, attach documentation fro Saleable Unit of Measure X hem/Each Box/Carton/Bundle/Inner Pack	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPPI er? tor? oduct? GTI aleable Quantity	Yes No No Yes No No Yes No	(DSCSA) INFOR	GLN: GCP: If yes, was or direct from m Provide source GTII 0033	0331722498975 Iginal product purchase fr? se manufacturer for rep 4-14 81722066600	ion fields are not applicable ded unit of Use GTIN-14	(Write-in, e.g	PH t to customer? j. 1 Vial) Weight Lbs. 0.16 Bundle/	Dimension Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width 1.85	hit to pharm. Each Gram Milliliter Its.) Height 3.23	Volume (Cube) 11.05	Pieces 1 24
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product sold by manufacturer's Is product sold by manufacturer's Has FDA granted waiver/exceptic If yes, attach documentation fro Saleable Unit of Measure x	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPPI er? tor? oduct? GTI aleable Quantity	Yes No No Yes No No Yes No	(DSCSA) INFOR	GLN: GCP: If yes, was or direct from m Provide source GTII 0033	0331722498975 Iginal product purchase fr? se manufacturer for rep 4-14 81722066600	ion fields are not applicable ded unit of Use GTIN-14	(Write-in, e.g	t to customer? j. 1 Vial) Weight Lbs. 0.16 Bundle/ 4.4 COST INFORMATION	Dimension Depth 1.85	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.85	hit to pharm. Each Gram Milliliter Its.) Height 3.23 4.5	Volume (Cube) 11.05	Pieces 1 24
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:					
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	Is the product a NIOSH hazardous drug? If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments					
ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:					
Is the Product						
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No 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:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	DUS 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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?