

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

Version 2021						Introduction T	ype: New Item		x Final Version			Date:	4/5/	/2023
			PRODUCT INFORMA	TION					SPECIAL HA	NDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Applicati	on: ANDA	a. Tempera	ture - Indicate the USP temp	erature range for	this product.			
Application Number for NDA/AN	NDA/BLA (drug); PI	MA/510(k)(med device	ce):	215	259				Temperature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applica	able:													
DUNS:	82-677-4775								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Levoth	nyroxine Sodium Tablets US						(write in)					
Selling Unit NDC:	31722-288-90		Unit of Use NDC:		31722-288-90		331722288903		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Levothyroxine So	odium Tablets USP, 10	00mcg						Is this product to be shippe				No	
									Is this product to be shippe	ed to customers on	dry ice?		No	
Active Ingredient(s):		Levothyroxine Sodi	um					h Contact f	ior tomporatura evaluacion a	unctions				
URL for Additional Product Inform	mation.	www.camberpharma	rom					D. Contact i	for temperature excursion q Name:	uestions.	Soma Raju			
Address:		Ave (and) 800 Center				Address 2:			Number:		732-529-04	23		
City:	Piscataway				State:	NJ	Zip : 08854		Group E-mail:		somaraju@	heterousa.cor	<u>n</u>	
Key Contact:	Customer Service	е			Email:		camberpharma.com							-
Phone Number:	1-866-827-3647	T.			Fax:	732-562-8788		c. Special r	egulations for product in an				No	_
Product Therapeutic Classification	on:	Synthetic Thyroid H	lormone						Special returns requirement	nts for this product?			No	
	ADDITI	IONAL PROPUST IN	FORMATION			DD ODLIGT D	ECODIDITION INCODINATION							7
	ADDITI	IONAL PRODUCT IN				PRODUCT D	ESCRIPTION INFORMATION	d. Store pro	oduct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product Orphan Drug Status	Unit of Use		Size:	90ct	e. Shelf life		(if different).			24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				100mcg		Initial shelf life at launch	(ir different):				Months
if yes, list NDCs of		140	FDA Approval Status			Strength:	roomog			ORDER INFOR	MATION			
component parts						Dosage Form	. Tablet							
reverse numbered?		No				Dosage i oilii	•		Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 9			
latex-free? preservative-free?		Yes No				Product Shap	capsule shaped, bicor tablets	nvex	Box/Carton Ampule		(Write-in, e	.g. 1 Box of 1	U Vials)	
correctional institution block?	•	No					Veller		Glass		Minimum o	rder quantity	2	Yes
opioid?		No				Product Colo	r:		Tube		William C	raci quantity	•	103
Cannabinoid?		No	Country of Origin	USA		Product Impr	plain on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					Product Impr	one side and debosse		Vial Liquid Multi			many of whi	ch package	type?
hospital scanning?			Is this product covered u				"score line 5" on the o	ther	Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes		side.		Vial Power Multi			Inner/Carton	/Pack	
			FOR GENERIC DRUG PR						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Aut	horized Generic	*If Authorized Generic, other		P	HARMACY ORDER	R / BILL UNIT			
L Orenzo Book Betimer	AB4				,,,,,		section fields are not applical	ble Rec sell un	nit to customer?			init to pharma		
I. Orange Book Rating: II. Generic Equivalent to What Bra		Thyro-Tabs					.,	itec. sell uli	iii to customer:		KX billing t	Each	acy:	
ii. Concre Equivalent to What Bre	ana .	myre rabe						(Write-in, e.	g. 1 Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	MATION			,	,			Milliliter		
				_										
Does supplier meet DSCSA defin		rer?	Yes	_	GLN:	0331722000000			ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?	•		No											
If yes, select exemption:					GCP:				Weight Lbs.		ions (US ms		Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		If was	ginal product purc	hacad	Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	'e avelusiva distribi	utor?	Yes		direct from m		nased	item/Each:	0.083	1.5	1.5	3	6.75	1
Has FDA granted waiver/exception			No				repackaged product	Box/Carton	/Bundle/					
If yes, attach documentation fro							.,	Inner Pack:						
								Case:	2.35	10	7	4.25	297.5	24
		GTI	N AND HIBCC PRODUCT I	NFORMATION					2.00			20	207.0	
Colooble Unit of Massure	_				071			Pallet:						
Saleable Unit of Measure x	٤	Saleable Quantity	HIBCC		GTIN	N-14 N-1722288903	Unit of Use GTIN-14 00331722288903							
					0033	22200303	00001122200000		COST INFORMATION			WHOLESALI	ER USE ONL	LY:
		24			1033	1722288900								
Box/Carton/Bundle/Inner Pack X Case								Regular Co	st		Vendor #:			
								Invoice Cos	st (WAC) (\$)	\$13.88	Whsl. Code	#:		
X Case								1.1						
X Case									4/5/0000		Fineline Co	de:		
X Case								As of date:	4/5/2023		Fineline Co	ode:		
X Case								As of date:	4/5/2023		Fineline Co	ode:		
X Case			Attach copy of SAFETY D	ATA SHEFT (SD	S) or non hazar	d letter, PACKAGE	INSERT, LABEL AND PHOTO				Fineline Co	ode:		



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	AZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
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 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? No	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#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP# ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments					
Is the Product	RETURN INSTRUCTIONS					
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No CLASS OF TRADE RESTRICTION: Controlled Substance Code Listed Chemical (List I or II) No No State Chemical (List I or II) No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	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) Comments:	If so, which states? Other requirements? Comments?					
MISCELLAI	IEOUS 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 fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:
F	Name: Phone:	Ships regular ground for 3-10 days receipt:
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:		Overnight receipt available:
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Infor	rmation Required to Process 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?
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?