

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

Version 2021						Introduction Typ	pe: New Item	n		x Final Version			Date:	4/5/	2023	
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215259							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:																
DUNS:	82-677-4775								`	Other Temperature Range	Requirement					
Proprietary Name (If Applicable) a		ame: Levo	thyroxine Sodium Tablets US							(write in)						
Selling Unit NDC:	31722-284-90		Unit of Use NDC:		31722-284-90		331722284905			Notes						
UDI			CVX Code:			MVX Code:			l I							
Description:	Levothyroxine So	dium Tablets USP, 2	25 mcg							Is this product to be shippe	d to customers on i	ce?		No		
										Is this product to be shipped	d to customers on o	dry ice?		No		
Active Ingredient(s): Levothyroxine Sodium																
						b. Contact for	r temperature excursion qu	estions:	O D - '							
URL for Additional Product Inform Address:		www.camberpharm				Address 2:				Name: Number:		Soma Raju 732-529-04	22			
City:	Piscataway					Zip: 08854			Group E-mail:				m			
Key Contact:	Customer Service	e			Email:	customerservice@d			Group 2 main			somaraju@heterousa.com				
Phone Number:	1-866-827-3647	-			Fax:	732-562-8788			c. Special red	julations for product in any	states?			No	1	
Product Therapeutic Classification	n:	Synthetic Thyroid	Hormone							Special returns requirement				No		
										-,					_	
	ADDITI	IONAL PRODUCT I	NFORMATION			PRODUCT DE	ESCRIPTION INFORMAT	TION	d. Store product (unit of sale) upright?							
The product is?			Is the Product	Direct-Ship	Only				•	Protect product (unit of sa	le) from light?			No	i	
a legend device?		No	Is the Product	Unit of Use	,		90ct		e. Shelf life:	. rotoot product (a.m. o. o.	,g			24	Months	
if yes, enter class #			Orphan Drug Status			Size:				Initial shelf life at launch (if different):				Months	
a product kit?		No				Strength:	25mcg								_	
if yes, list NDCs of			FDA Approval Status			Su engui.					ORDER INFORM	MATION				
component parts						Dosage Form:	Tablet									
reverse numbered?		No								Unit of Sale			NDC selling	unit?		
co-licensed? latex-free?		No Yes	Allergens Present				annaula abanaul b	in a municipal of		x Bottle Box/Carton		1 bottle of 9		0 \ /:ala\		
preservative-free?		No.				Product Shape	capsule shaped, b tablets	olconvex		Ampule		(vvnie-in, e	.g. 1 Box of 1	u viais)		
correctional institution block?		No					Orongo			Glass		Minimum o	rder quantity	12	Yes	
opioid?		No				Product Color:	·			Tube			ruor quantity	•	103	
Cannabinoid?		No	Country of Origin	USA		Book to the section of	plain on one side,			Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	init dose for					Product Imprir	debossed "score li	ine 1"		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?	
hospital scanning?			Is this product covered u				on other			Vial Powder Sql		24	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes					Vial Power Multi			Inner/Cartor	/Pack		
										Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCTS												
							of Audharian I Canada and			DI.	ARMACY ORDER	/ DILL LINIT				
				_	Au		If Authorized Generic, oth section fields are not appl				ARWACT ORDER					
I. Orange Book Rating:	AB4	The are Table					section fields are flot appl	ilodbio	Rec. sell unit	to customer?	1	Rx billing u	nit to pharm	асу:		
II. Generic Equivalent to What Bra	nd?:	Thyro-Tabs							(Write-in, e.g.	1 \/ial\			Each Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(vviite-iii, e.g.	. i viai)			Milliliter				
Does supplier meet DSCSA definit	tion of manufactu	rer?	Yes		GLN:	0331722000000				ITEN	I AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:					\A/a:ab4 b -	Dimensi	ions (US msr	nts.)	Volume	Saleable #	
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No			iginal product purch	ased		Item/Each:	0.083	1.5	1.5	3	6.75	1	
Is product sold by manufacturer's			Yes		direct from m						1.0	1.0		0.70	·	
Has FDA granted waiver/exception		roduct?	No		Provide source	e manufacturer for i	repackaged product		Box/Carton/B	Sundle/						
If yes, attach documentation from	n FDA.								Inner Pack: Case:							
		GT	IN AND HIBCC PRODUCT I	NEORMATION					Case.	2.35	10	7	4.25	297.5	24	
			TO THE OF	onATTON					Pallet:							
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN	V-14	1 4.101.							
X Item/Each	•	1				31722284905	00331722284905									
Box/Carton/Bundle/Inner Pack										COST INFORMATION			WHOLESAL	ER USE ONL	_Y:	
X Case		24			1033	31722284902				· · · · · · · · · · · · · · · · · · ·						
Pallet									Regular Cost			Vendor #:				
									Invoice Cost	(WAC) (\$)	\$9.31	Whsl. Code				
	-								An of date	4/5/2023		Fineline Co	de:			
	-								As of date:	4/3/2023		-				
	_															
l '			Attach copy of SAFETY D	ATA SHEET (SI	DS) or non hazai	rd letter, PACKAGE IN	NSERT, LABEL AND PHO	OTO OF P	RODUCT PACK	AGING and BARCODE		-				
*Please provide any additional info	ormation on page	2.	, 0. 0 271 0/	(01	-, -:		esignated Drop Ship Or			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? 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 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? 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?					