

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

Version 2021					Introduction Type	: New Item		x Final Version			Date:	6/23	3/2024
		PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	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); F	MA/510(k)(med device	e):	215	5259			1	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicable:							† I	_					
DUNS: 11-856-3719							*	Other Temperature Range I	Requirement	Excursions a	allowed between	en 15° and 3	30°C (59°
Proprietary Name (If Applicable) and Established N	lame: Levothy	roxine Sodium Tablets, US	SP 75 mcg				I	(write in)		and 86°F)			
Selling Unit NDC: 31722-286-10		Unit of Use NDC:				1722286107		Notes					
UDI		CVX Code:			MVX Code:		1						
Description: Levothyroxine S	odium Tablets, USP 75	mcq					Ţ	Is this product to be shipped	d to customers on	ce?		No	7
		· ·						Is this product to be shipped				No	1
Active Ingredient(s):	Levothyroxine sodiu	m, USP					1						-
							b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Information:	www.camberpharma	.com						Name:		Soma Raju			
Address: 800 Centennial	Ave, Suite 1				Address 2:			Number:		732-529-042			
City: Piscataway				State:		p: 08854	-	Group E-mail:		somaraju@h	neterousa.com	<u>m</u>	
Key Contact: Customer Service				Email:	customerservice@car	mberpharma.com			-1-10			NI.	7
Phone Number: 1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any				No	-
Product Therapeutic Classification:	Synthetic thyroid hor	mone						Special returns requirement	s for this product?			No	
4000	FIGNIAL PROBLECT INF	CODMATION			BRODUOT DEG	ODIDTION INFORMATION							7
ADDI	TIONAL PRODUCT INF	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	_
The product is?		Is the Product	Direct-Ship C	nly				Protect product (unit of sa	ile) from light?			No	
a legend device?	No	Is the Product	Neither		Size:	1000 ct	e. Shelf life:					24	Months
if yes, enter class #	I	Orphan Drug Status						Initial shelf life at launch (if different):				Months
a product kit?	No	EDA 4			Strength:	75 mcg			ORDER INFORI	MATION			
if yes, list NDCs of		FDA Approval Status				Tablet			ORDER INFORI	MATION			
component parts reverse numbered?	No				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present						x Bottle		1 Bottle of 1		uiii.	
latex-free?	Yes					Capsule, biconvex		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?	No	Alcohol,	Sugar, Dye		Product Shape:			Ampule		(g	,	
correctional institution block?	No				Product Color:	Violet		Glass		Minimum o	der quantity	<i>i</i> ?	Yes
opioid?	No				Product Color:			Tube					
Cannabinoid?	No	Country of Origin	USA		Product Imprint:	Plain on one side and debossed 'score line 3' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unit dose for					r roduct imprint.	score line 3 on the other side		Vial Liquid Multi				ich package	type?
hospital scanning?		Is this product covered u						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	Yes				Vial Powder Multi			Inner/Cartor	n/Pack	
]	Other: Write In			Case		
		FOR GENERIC DRUG PR	ODUCTS										
								DI.	ARMAOV ORRE	/ DILL LINET			
				Au		Authorized Generic, other ction fields are not applicable			ARMACY ORDER				
I. Orange Book Rating: AB4					560	ction fields are not applicable	Rec. sell unit	to customer?	-	Rx billing u		acy:	
II. Generic Equivalent to What Brand?:	Thyro-Tabs							4 1 5 5			Each		
	DDIJC CUDDI V	Y CHAIN SECURITY ACT ((Decea) INFOR	MATION			(Write-in, e.g	. 1 Vial)			Gram		
	DRUG SUPPL	T CHAIN SECURITY ACT	(DSCSA) INFOR	MATION							Milliliter		
Does supplier meet DSCSA definition of manufact	urer?	Yes	T	GLN:	0331722498975			ITEN	I AND PACKING I	NEORMATIO	V		
Is product exempt from DSCSA?	urer.	No		OLIV.	0001122430310				.,	5	•		
If yes, select exemption:		·		GCP:			il		Dimens	ions (US msn	nte \	Volume	Saleable #
If yes, select exemption: Other exemption - Write in:				GUP:			1	Weight Lbs.	Dimens	Width	•	(Cube)	Saleable # Pieces
Is product repackaged?		No		If yes was a	riginal product purchas	hes	Item/Each:		T	1	Height		
Is product sold by manufacturer's exclusive distril	outor?	Yes		direct from m		Jeu	nem/Lucii.	0.34	2.25	2.25	4.25	21.52	1
Has FDA granted waiver/exception/exemption for		No	_		 ce manufacturer for rep	packaged product	Box/Carton/E	Bundle/					
If yes, attach documentation from FDA.							Inner Pack:						
							Case:	8.55	14.5	10	5	725	24
	GTIN	I AND HIBCC PRODUCT I	NFORMATION					8.55	14.5	10	5	725	24
							Pallet:						
Saleable Unit of Measure	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each	1			003	31722286107								
Box/Carton/Bundle/Inner Pack								COST INFORMATION			WHOLESAL	ER USE ONL	_Y:
X Case	24			103	31722286104								
Pallet							Regular Cos			Vendor #:	ш.		
							Invoice Cost	(VVAC) (\$)	\$147.89	Whsl. Code			
							As of date:	3/13/2023		Fineline Co	uc.		
							As of date.	5, .5,2025					
		Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	ard letter, PACKAGE INS	SERT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE.					



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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	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:					



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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?