

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

Version 2021						introduction i	ype:	New Item	X	Final Version			Date:	4/5/	2023
			PRODUCT INFORMAT	ION						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/ANI	tion 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									emperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Levothy	roxine Sodium Tablets USP	, 200mcg						rite in)					
Selling Unit NDC:	31722-294-10		Unit of Use NDC:				331722294	4102	Notes						
UDI			CVX Code:			MVX Code:									
Description: Levothyroxine Sodium Tablets USP, 200mcg Is this product to be shipped to customers on ice?										No					
								Is this p	roduct to be shipped	d to customers on d	try ice?		No		
Active Ingredient(s): Levothyroxine Sodium															
								b. Contact for tempera	ature excursion qu	estions:	0 0 :				
URL for Additional Product Inform		www.camberpharma.c				A d due a a O .			Name:			Soma Raju			
Address: City:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 Piscataway State:				Address 2:	Zin: 00	0054	Numbe			732-529-042				
Key Contact:	Customer Service	2			Email:	-	Zip: 08854 Group E-mail: somara				somarajuer	naraju@heterousa.com			
Phone Number:	1-866-827-3647					732-562-8788							No	1	
Product Therapeutic Classification		Synthetic Thyroid Ho	rmone		· un	102 002 0100				returns requirement				No	
Product Therapeutic Glassification		Cynthicae Thyrola Flo	imone						Оресіаі	returns requirement	s for this product:			140	
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT D	DESCRIPTION	ON INFORMATION	d. Store product (unit	of cale) unright?				No	1
	ADDITI	ONAL I RODOOT IN		Discoul Ohio O		TRODUCTE	JEGORIII TIR	ON IN ORMATION]
The product is?			Is the Product	Direct-Ship Or Neither	niy		100			product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100	OOCt	e. Shelf life:	b - 16 116 4 1 b - 6				24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				200)mag	initiai s	helf life at launch (ir different):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength: 200mcg			ORDER INFORMATION						
component parts			i DA Appiovai Status				Tab	olet			ORDER IN ORI	IATION			
reverse numbered?		No				Dosage Form	n:	,,,,,,	Unit of	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 bottle of 10			
latex-free?		Yes				Bara da and Oliver	cap	sule shaped, biconvex		Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?		No				Product Shap	pe: tabl			Ampule			•	,	
correctional institution block?		No				Product Colo	Pinl	k		Glass		Minimum or	der quantity	?	Yes
opioid?		No				r rounct colo	,,			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Impr		in on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					oddot iiiipi	deb	possed "1 score line 1"		Vial Liquid Multi			many of whi	ch package t	type?
hospital scanning?			Is this product covered un				on t	the other side.		Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA	AA)?	Yes					Vial Power Multi			Inner/Carton	Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCTS											
				1	A	harinad Casaria	*16 ^	and Conneils other		DU	ARMACY ORDER	/ DILL LINIT			
					Aui	horized Generic		zed Generic, other lds are not applicable			ARMACT ORDER				
	AB4						Section nei	ius are not applicable	Rec. sell unit to custo	mer?	1	Rx billing u	nit to pharma	icy:	
II. Generic Equivalent to What Brand?: Thyro-Tabs							Each								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g. 1 Vial)				Gram Milliliter				
		DRUG SUFFEI	CHAIN SECONTT ACT (D	JOSA) IN OK	MATION								wiiiiitei		
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes	Т	GLN:	0331722000000				ITEN	AND PACKING IN	NEORMATIO	N		
Is product exempt from DSCSA?			No	-	02.1.	0001122000000									
If yes, select exemption:					GCP:						Dimenei	ons (US msn	nte \	Volume	Saleable #
Other exemption - Write in:					GUF.				1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes was or	iginal product purc	chased		Item/Each:		1				
Is product repaininged:	exclusive distribu	utor?	Yes		direct from m					0.33	2.25	2.25	4.25	21.52	1
Has FDA granted waiver/exception			No			e manufacturer for	r repackage	ed product	Box/Carton/Bundle/						
If yes, attach documentation fron				·				·	Inner Pack:						
									Case:	8.5	14.5	10	5	725	24
		GTIN	AND HIBCC PRODUCT IN	FORMATION						0.5	14.5	10	3	125	24
									Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTIN		Ur	nit of Use GTIN-14							
X Item/Each		1			0033	31722294102	L			T INFORMATION			MILOI EQUA	D LIGHT CH	v -
Box/Carton/Bundle/Inner Pack									COS	ST INFORMATION			WHOLESALE	R USE ONL	.Y:
X Case		24			1033	31722294109	-		Bogular Coot			Vander #			
Pallet	1						-		Regular Cost Invoice Cost (WAC) (\$	1	\$202.67	Vendor #: Whsl. Code	#-		
									MIVOICE COST (VVAC) (\$,	\$202.67	Fineline Co			
	-								As of date:	4/5/2023		i illellile CO	uc.		
	1								1.00.00			1			
			Attach copy of SAFETY DAT	A SHEET (SDS	S) or non hazar	d letter, PACKAGE	INSERT, LA	ABEL AND PHOTO OF P	PRODUCT PACKAGING ar	nd BARCODE.					
*Please provide any additional info	ormation on page		· ·		-	See new p. 3 for			Signatu						
· ·	. •														



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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 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?