

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

Version 2021						Introduction Typ	ne: New Item			x Final Version			Date:	6/23/	3/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a.	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		and 25 C (68	s° – 77° F)		
Medical Device Class, if applica										· -					
DUNS:	11-856-3719									Other Temperature Range F	Requirement	Excursions a	allowed between	en 15° and 3	30°C (59°
Proprietary Name (If Applicable) a	and Established Na	ime: Levo	thyroxine Sodium Tablets, US							(write in)		and 86°F)			
Selling Unit NDC:	31722-288-90		Unit of Use NDC:		31722-288-90		31722288903			Notes					
UDI			CVX Code:			MVX Code:									
Description:	Levothyroxine Soc	dium Tablets, USP	100 mcg							Is this product to be shipped	to customers on i	e?		No	1
_	-									Is this product to be shipped				No	1
Active Ingredient(s): Levothyroxine sodium, USP															
							b.	. Contact for	temperature excursion que	estions:					
URL for Additional Product Inform		www.camberpharn	na.com							Name:		Soma Raju			
Address:	800 Centennial Av	/e, Suite 1			Ctata	Address 2:	71			Number:		732-529-042			
City:	Piscataway Customer Service				State: Email:	NJ customerservice@c	Zip: 08854			Group E-mail:		somaraju@f	neterousa.cor	<u>n</u>	
Key Contact: Phone Number:	1-866-827-3647	!			Fax:	732-562-8788	amberphama.com		Cnoolal roa	ulations for product in any	ctotoo?			No	٦
Product Therapeutic Classification		Synthetic thyroid h	ormone		ı ax.	732-302-0700		C.	Special reg	Special returns requirement				No	-
Product Therapeutic Classification	on:	Synthetic triyroid i	lormone							Special returns requirement	s for this product?			INO	_
	ADDITIO	ONAL PRODUCT II	NEORMATION			PRODUCT DE	SCRIPTION INFORMATION	N d	l Store produ	uct (unit of sale) upright?				No	٦
	ADDITIO	ONALT NODOOT II		Discoul Ohio O	and the	T RODOOT DE	CORIN TION IN ORMATIC	u.	i. Store prou						-
The product is?		NI.	Is the Product	Direct-Ship C Unit of Use	inly		00 -1		01-1/11/-	Protect product (unit of sa	le) from light?			No 04	
a legend device? if yes, enter class #		No	Is the Product	Offit of Ose		Size:	90 ct	e.	. Shelf life:	Initial abolf life at laurab (if different).			24	Months Months
a product kit?		No	Orphan Drug Status				100 mcg			Initial shelf life at launch (r amerent):				Wonths
if yes, list NDCs of		140	FDA Approval Status			Strength:	100 meg				ORDER INFORM	IATION			
component parts			1 5717 pp. o vai o tatao				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 9	0 Tablets		
latex-free?		Yes	Alcohol	Sugar, Dye		Product Shape	Capsule, biconvex			Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No	Alcohol,	ougui, byc		1 Todact Griape	•			Ampule					
correctional institution block?		No				Product Color:	Yellow			Glass		Minimum o	der quantity	?	Yes
opioid?		No								Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprin	Plain on one side and debosse 'score line 5' on the other side	d		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		In this was done to account to	and a the		•				Vial Liquid Multi Vial Powder Sql			many of whi	ch package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered to Trade Agreements Act (Yes					Vial Powder Sgi Vial Powder Multi		24	Inner/Cartor	/Dook	
II Offic Dose, indicate NDC fiele.			Trade Agreements Act (IAA):	162					Other: Write In			Case	/rack	
			FOR GENERIC DRUG PR	CODUCTS						Other. Write III			Ousc		
			TOR GENERIC DROGT	1000013											
					Aut	horized Generic *I	If Authorized Generic, othe			PH	ARMACY ORDER	/ BILL UNIT			
L Oranga Baak Batings	AB4			_	7.00		ection fields are not applica		Pac call unit	to customer?					
I. Orange Book Rating: II. Generic Equivalent to What Bra		Thyro-Tabs							vec. sen unit	to customer:	1	KX billing u	nit to pharma Each	acy:	
ii. Generic Equivalent to what Bra	anu r.	THYIO-TADS							(Write-in, e.g.	1 Vial)	J		Gram		
		DRUG SUPF	PLY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION			,	(*************************************	· viai,			Milliliter		
				,											
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes		GLN:	0331722498975				ITEN	I AND PACKING II	IFORMATIO	٧		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					100	Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was ori	ginal product purcha	ased	Ite	tem/Each:	0.08	1.5	1.5	3	6.75	1
Is product sold by manufacturer's			Yes	_	direct from mi						1.5	1.0	3	0.75	'
Has FDA granted waiver/exception		oduct?	No		Provide source	e manufacturer for r	epackaged product		Box/Carton/B	undle/					
If yes, attach documentation fro	m FDA.								nner Pack:						
		61	TIN AND HIBCC PRODUCT I	NEODMATION				c	Case:	2.35	10	7	4.25	297.5	24
		G	TIN AND HIBCC PRODUCT I	NFURMATION					Pallet:						
Saleable Unit of Measure		aleable Quantity	HIBCC		GTIN	1.14	Unit of Use GTIN-1	111-	anet:						
X Item/Each	5	1	TIIDOO			1722288903	00331722288903	<u> </u>							
Box/Carton/Bundle/Inner Pack										COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			1033	1722288900									
Pallet					1			R	Regular Cost			Vendor #:			
								In	nvoice Cost ((WAC) (\$)	\$13.88	Whsl. Code	#:		
												Fineline Co	de:		
								A	As of date:	3/13/2023		ļ			
11															
*Please provide any additional inf			Attach copy of SAFETY D	ATA SHEET (SD	S) or non hazar		ISERT, LABEL AND PHOT esignated Drop Ship Only		DUCT PACKA	GING and BARCODE. 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? 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?