

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

Version 2021						Introduction Type	e: New Item		x Final Version			Date:	4/5/	/2023
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application	: ANDA	a. Temperatu	re - Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN	NDA/BLA (drug); PI	MA/510(k)(med devi	ce):	21	5259		<u> </u>		Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica	able:													
DUNS:	82-677-4775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)		ame: Levoth	hyroxine Sodium Tablets US					I	(write in)					
Selling Unit NDC:	31722-291-90		Unit of Use NDC:		31722-291-90		1722291903		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Levothyroxine So	odium Tablets USP, 13	37mcg						Is this product to be shippe	d to customers on i	ce?		No	1
									Is this product to be shippe	d to customers on o	try ice?		No	
Active Ingredient(s):		Levothyroxine Sodi	um											
l	_							b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharma				Address O.		-	Name:		Soma Raju	20		
Address: City:	Piscataway	Ave (and) 800 Center	iniai Ave, Suite 1		State:	Address 2:	ip: 08854	-	Number: Group E-mail:		732-529-042			
Key Contact:	Customer Service	0			Email:	customerservice@ca		-	Group E-mail:		somaraju@i	neterousa.com	<u>11</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	miscrphama.com	c Special re	gulations for product in any	states?			No	1
Product Therapeutic Classification		Synthetic Thyroid H	formone					or openiar re	Special returns requiremen				No	1
l rough morapouno olacomouno		-,							opoolal rotarrio roquirorriorr	o for ano product.				7
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store proc	luct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship	Only				Protect product (unit of sa	ula) from light?			No	i
a legend device?		No	Is the Product	Unit of Use	Office		90ct	e. Shelf life:	Frotect product (unit of Se	ile) iroin light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	3001	c. onen me.	Initial shelf life at launch (	if different):			24	Months
a product kit?		No				a	137mcg							
if yes, list NDCs of			FDA Approval Status			Strength:	, and the second			ORDER INFORM	MATION			
component parts						Dosage Form:	Tablet							
reverse numbered?		No				Dosage i oiii.			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 9			
latex-free?		Yes				Product Shape:	capsule shaped, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No					tablets		Ampule					
correctional institution block? opioid?		No No				Product Color:	Turquoise		Glass Tube		Minimum o	rder quantity	1?	Yes
Cannabinoid?		No	Country of Origin	USA			plain on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	Country of Origin	00/1		Product Imprint	debossed "score line 8"		Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?	driit dosc foi		Is this product covered u	under the			on the other side.		Vial Powder Sql			Each	on paonago	type.
If Unit Dose, indicate NDC here:			Trade Agreements Act (		Yes				Vial Power Multi			Inner/Cartor	n/Pack	
			_						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Aut		Authorized Generic, other		Pł	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4					se	ction fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Thyro-Tabs										Each	•	
								(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPPL	LY CHAIN SECURITY ACT (	(DSCSA) INFO	RMATION							Milliliter		
			W	_					IT.	A AND DAOKING I	VEODMATIO	NI.		
Does supplier meet DSCSA defin		rer?	Yes No	_	GLN:	0331722000000			IIE	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			140					1			0/2	-4-3		
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msr		Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		W	inimal mandood		Item/Each:		Depth	Width	Height	(Cube)	Pieces
	a avaluaiva diatribu	utor?	Yes	_	If yes, was or direct from m	iginal product purcha	sed	Item/Each:	0.083	1.5	1.5	3	6.75	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	-		ir r se manufacturer for re	nackaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro		Todaot.			Trovide Source	oc manufacturer for re	packagea product	Inner Pack:	Junuici					
. , ,								Case:	0.05	40	-	4.05	007.5	0.4
		GTI	IN AND HIBCC PRODUCT I	NFORMATION					2.35	10	7	4.25	297.5	24
								Pallet:						
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC		GTII		Unit of Use GTIN-14							
X Item/Each		1			0033	31722291903	00331722291903							
									COST INFORMATION			WHOLESAL	ER USE ONL	LY:
Box/Carton/Bundle/Inner Pack					1033	31722291900					1			
X Case		24									Manual "			
		24						Regular Cost		040.00	Vendor #:	4.		
X Case		24						Regular Cost Invoice Cost		\$13.90	Whsl. Code			
X Case		24						Invoice Cost		\$13.90				
X Case		24							(WAC) (\$)	\$13.90	Whsl. Code			
X Case		24						Invoice Cost	(WAC) (\$)	\$13.90	Whsl. Code			
X Case		24	Attach copy of SAFETY D/	ATA SHEET (S)	DS) or non hazar	rd letter, PACKAGE INS	SERT, LABEL AND PHOTO OF F	Invoice Cost As of date:	(WAC) (\$) 4/5/2023	\$13.90	Whsl. Code			



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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 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?