

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

Version 2021						Introduction Type	: New Item		x Final Version			Date:	4/5/	/2023
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperat	ure - Indicate the USP temp	erature range for t	his 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					I	(write in)					
Selling Unit NDC:	31722-285-10		Unit of Use NDC:				1722285100		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Levothyroxine So	dium Tablets USP, 5	50mcg					T	Is this product to be shippe	d to customers on i	ce?		No	
								11	Is this product to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s): Levothyroxine Sodium							_							
URL for Additional Product Information: www.camberpharma.com						b. Contact fo	or temperature excursion qu	estions:	0 D - '-					
Address:		www.camberpharm				Address 2:		+	Name: Number:		Soma Raju 732-529-042	22		
City:	Piscataway					<b>p</b> : 08854	1	Group E-mail:			neterousa.com	m		
Key Contact:	Customer Service	9					mberpharma.com	Straig St						
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any	states?			No	1
Product Therapeutic Classificatio	n:	Synthetic Thyroid	Hormone						Special returns requiremen	s for this product?			No	1
-					_									1
	ADDITI	ONAL PRODUCT II	NFORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product (unit of sale) upright?						
The product is?			Is the Product	Direct-Ship (	Only	1			Protect product (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	1000ct	e. Shelf life:	, ,	,			24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	50mcg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	MATION			
component parts reverse numbered?		NI.				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present						x Bottle		1 bottle of 1		uiiit:	
latex-free?		Yes	Allergens i resent				capsule shaped, biconvex		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape:	tablets		Ampule		(	g =		
correctional institution block?		No				Product Color:	White		Glass		Minimum o	rder quantity	1?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	plain on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for						one side and debossed		Vial Liquid Multi				ich package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered under the Agreements Act (		Vaa		"score line 2" on the other side.		Vial Powder Sql Vial Power Multi		24	Each Inner/Cartor	/Deels	
ii Onit Dose, indicate NDC here:			Trade Agreements Act (	IAA)!	Yes		oldo:		Other: Write In			Case	I/Pack	
			FOR GENERIC DRUG PR	ODUCTS				1	Galer. Write in			Joase		
			TOR GENERIO BROOT R	000010										
					Au	thorized Generic *If	Authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4					sec	ction fields are not applicable	Rec. sell uni	t to customer?		Rx billing u	nit to pharm	acv.	
II. Generic Equivalent to What Bra	ınd?:	Thyro-Tabs						T I				Each	,-	
·								(Write-in, e.g. 1 Vial) Gram						
		DRUG SUPP	LY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION							Milliliter		
December 11 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1			Vee	_	01.11	000470000000			ITE	I AND PACKING I	NEODMATIO	N.		
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes No	_	GLN:	0331722000000			1151	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			110					-		B!	(UO	\		
If yes, select exemption:					GCP:			1	Weight Lbs.		ions (US msn	•	Volume (Cube)	Saleable # Pieces
Other exemption - Write in: Is product repackaged?			No		If you was a	riginal product purchas	ha	Item/Each:		Depth	Width	Height	(Cube)	
Is product repackaged:	exclusive distrib	utor?	Yes	_	direct from m		eu	item/Each.	0.33	2.25	2.25	4.25	21.52	1
Has FDA granted waiver/exceptio			No			ce manufacturer for re	packaged product	Box/Carton/	Bundle/					
If yes, attach documentation from								Inner Pack:						
								Case:	8.5	14.5	10	5	725	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION					0.0					
Optoble Heller of Manager	_							Pallet:						
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC			N-14 31722285100	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack					003	31722203100			COST INFORMATION			WHOI ESAL	ER USE ONL	γ
X Case		24			103	31722285107			- 0001 INI ORIMATION				LIN GOL ONE	
Pallet					.00			Regular Cos	t		Vendor #:			
								Invoice Cost		\$144.67	Whsl. Code	#:		
								[]			Fineline Co			
								As of date:	4/5/2023					
<del> </del>			Attack conv COAFETY CO	TA CUEET (CO	201		EDT LADEL AND DUOTE OF	II	ACING and DADGODE		1			
*Please provide any additional inf	ormation on no	2	Attach copy of SAFETY DA	ATA SHEET (SL	or non naza رحر		ERT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE.  Signature:					
*Please provide any additional inf	ormation on page	4.				see new p. s for Des	ignated Drop Ship Only.		orgnature:					



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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 conficunt 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?					