

# **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	IDLING 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); P	MA/510(k)(med devi	ce):	21	5259				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica														
DUNS:	82-677-4775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)		ame: Levot	hyroxine Sodium Tablets US						(write in)					
Selling Unit NDC:	31722-287-90		Unit of Use NDC		31722-287-90		722287906		Notes					
UDI			CVX Code:			MVX Code:		I						
Description:	Levothyroxine Sc	dium Tablets USP, 8	8mcg					T	Is this product to be shippe	d to customers on i	ce?		No	
									Is this product to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s):		Levothyroxine Sod	ium					11		_				
LIDI for Additional Bradust Information								b. Contact fo	r temperature excursion qu	estions:	Cama Daiu			
URL for Additional Product Inform Address:		www.camberpharma Ave (and) 800 Center			1	Address 2:		+	Name: Number:		Soma Raju 732-529-042	22		
City:	Piscataway	Ave (and) 000 Center	Tirilai Ave, Suite 1		State:		p: 08854	-	Group E-mail:			neterousa.com	m	
Key Contact:	Customer Service	e			Email:	customerservice@car		1	o.oup 2 mam		<u>somaraja o</u>	101010404.00	<u></u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	gulations for product in any	states?			No	
Product Therapeutic Classification	on:	Synthetic Thyroid H	Hormone					'   ·	Special returns requiremen				No	
										•				1
	ADDIT	IONAL PRODUCT IN	IFORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only			1	Protect product (unit of sa	ale) from light?			No	İ
a legend device?		No	Is the Product	Unit of Use	-	Ci	90ct	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:	88mcg							
if yes, list NDCs of			FDA Approval Status			ou ongun				ORDER INFORM	MATION			
component parts		1				Dosage Form:	Tablet		11-2-40-1-		VA/Ib ad in die	NDC asilina		
reverse numbered? co-licensed?		No No	Allergens Present						Unit of Sale x Bottle		1 bottle of 9	NDC selling	unit?	
latex-free?		Yes	Allergens Fresent				capsule shaped, biconvex		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape:	tablets		Ampule		(WINC III, C	.g. 1 Dox 01 1	o viais)	
correctional institution block?		No				Description Colors	Olive		Glass		Minimum o	rder quantity	1?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	plain on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					1 roduct imprint.	one side and debossed		Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered				"score line 4" on the other side.		Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)?	Yes		side.		Vial Power Multi			Inner/Cartor	n/Pack	
			FOR GENERIC DRUG PF	OBLICTO				1	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Aut	horized Generic *If	Authorized Generic, other		Pl	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4						tion fields are not applicable	Rec sell unit	to customer?			nit to pharm	201/1	
II. Generic Equivalent to What Bra		Thyro-Tabs						Titee. Sen unit	to customer.		KX Dillilly u	Each	acy.	
ii. Generie Equivalent to What Bre	unu	myro rabo						(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION			, ,				Milliliter		
				_										
Does supplier meet DSCSA defin		rer?	Yes		GLN:	0331722000000			ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No					-						
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msr	•	Volume	Saleable #
Other exemption - Write in:			M.						g LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		10	No Yes	_		ginal product purchas	ed	Item/Each:	0.083	1.5	1.5	3	6.75	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	-	direct from mi	rr ? se manufacturer for rep	ackaged product	Box/Carton/E	Rundle/					
If yes, attach documentation fro	nivexemplion for p	TOUUCI:	140		r rovide sourc	e manufacturer for rep	ackageu product	Inner Pack:	Juliule/					
	m FDA							Case:						
ii yes, attacii documentation iro	om FDA.							1	2.35	10	7	4.25	297.5	24
ii yes, attach documentation no	om FDA.	GT	IN AND HIBCC PRODUCT I	NFORMATION					2.00					
ii yes, attach documentation no	om FDA.	GT	IN AND HIBCC PRODUCT	NFORMATION				Pallet:	2.00					
Saleable Unit of Measure		GT Saleable Quantity	IN AND HIBCC PRODUCT	NFORMATION	GTIN		Unit of Use GTIN-14	Pallet:	2.55					
Saleable Unit of Measure				NFORMATION		N-14 81722287906	Unit of Use GTIN-14 00331722287906	Pallet:						
Saleable Unit of Measure    X		Saleable Quantity		NFORMATION	0033	31722287906		Pallet:	COST INFORMATION			WHOLESAL	ER USE ONL	Y:
Saleable Unit of Measure  X Item/Each Box/Carton/Bundle/Inner Pack X Case		Saleable Quantity		NFORMATION	0033				COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
Saleable Unit of Measure    X		Saleable Quantity		NFORMATION	0033	31722287906		Regular Cost	COST INFORMATION		Vendor #:		ER USE ONL	Y:
Saleable Unit of Measure  X Item/Each Box/Carton/Bundle/Inner Pack X Case		Saleable Quantity		NFORMATION	0033	31722287906			COST INFORMATION		Vendor #: Whsl. Code	#:	ER USE ONL	.Y:
Saleable Unit of Measure  X Item/Each Box/Carton/Bundle/Inner Pack X Case		Saleable Quantity		NFORMATION	0033	31722287906		Regular Cost	COST INFORMATION		Vendor #:	#:	ER USE ONL	Y:
Saleable Unit of Measure  X Item/Each Box/Carton/Bundle/Inner Pack X Case		Saleable Quantity		NFORMATION	0033	31722287906		Regular Cost	COST INFORMATION		Vendor #: Whsl. Code	#:	ER USE ONL	Y:
Saleable Unit of Measure  X   tem/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity		NFORMATION	0033	31722287906		Regular Cost	COST INFORMATION		Vendor #: Whsl. Code	#:	ER USE ONL	Y:
Saleable Unit of Measure  X   tem/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity	HIBCC		1033	81722287906 81722287903		Regular Cost Invoice Cost As of date:	COST INFORMATION : (WAC) (\$)  4/5/2023		Vendor #: Whsl. Code	#:	ER USE ONL	Y:



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

#### Version 2021

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 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?