

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

Version 2021						Introduction Typ	e: New Item		x Final Version			Date:	6/23	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOF	RAGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	n: ANDA	a. Temperatur	e - Indicate the USP tempe	rature 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:	11-856-3719								Other Temperature Range F	Requirement	Excursions a	Illowed betwe	en 15° and 3	30°C (59°
Proprietary Name (If Applicable) as	nd Established Na	me: Levo	thyroxine Sodium Tablets, US	P 100 mcg					(write in)	·	and 86°F)			
Selling Unit NDC:	31722-288-10		Unit of Use NDC:				31722288101		Notes					
UDI			CVX Code:			MVX Code:								
Description: Levothyroxine Sodium Tablets, USP 100 mcg Is this product to be shipped to customers on ice? No								1						
	,								Is this product to be shipped				No	
Active Ingredient(s): Levothyroxine sodium, USP									•			_		
							b. Contact for	temperature excursion que	estions:					
URL for Additional Product Inform		www.camberpharr	na.com						Name:		Soma Raju			
Address:	800 Centennial Av					Address 2:			Number:		732-529-042			
City:	Piscataway				State:		Zip: 08854		Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service	!			Email:	customerservice@c	amberpharma.com						7	
Phone Number:	1-866-827-3647	la			Fax:	732-562-8788		c. Special regulations for product in any states?					No	-
Product Therapeutic Classification	1:	Synthetic thyroid I	normone						Special returns requirement	s for this product?			No	
								- 1						-
	ADDITIO	ONAL PRODUCT I	NFORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nly				Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	1000 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.			Initial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	100 mcg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	MATION			
component parts		ls:				Dosage Form:	Tablet		11-2		M/hat in the	NDC aalliaa		
reverse numbered?		No	Allermana Dracent						Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Capsule, biconvex		x Bottle Box/Carton		1 Bottle of 10 (Write-in, e.g		O Viole)	
preservative-free?		No	Alcohol,	Sugar, Dye		Product Shape:	Capsule, bicorivex		Ampule		(vviite-iii, e.	y. 1 bux 01 11	U Viais)	
correctional institution block?		No					Yellow		Glass		Minimum or	der auantity	12	Yes
opioid?		No				Product Color:	T CIIOW		Tube			uci quantity		103
Cannabinoid?		No	Country of Origin	USA			Plain on one side and debossed		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		, ,			Product Imprin	'score line 5' on the other side		Vial Liquid Multi		If Yes, how i	many of whi	ch package	type?
hospital scanning?			Is this product covered u	inder the					Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ГАА)?	Yes				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											_			
					Au		f Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4					Se	ection fields are not applicable	Rec. sell unit	to customer?		Rx billing ur	nit to pharma	асу:	
II. Generic Equivalent to What Brand?: Thyro-Tabs					Each			-						
						(Write-in, e.g. 1 Vial)								
		DRUG SUPF	PLY CHAIN SECURITY ACT (DSCSA) INFOR	MATION							Milliliter		
		_		_										
Does supplier meet DSCSA definit	ion of manufactur	er?	Yes	_	GLN:	0331722498975			IIEM	AND PACKING II	NFORMATION	N		
Is product exempt from DSCSA?			No					4						
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm	•	Volume	Saleable #
Other exemption - Write in:									.reigin Lb3.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		iginal product purcha	sed	Item/Each:	0.34	2.25	2.25	4.25	21.52	1
Is product sold by manufacturer's			Yes No	-	direct from m			Dev/0						
Has FDA granted waiver/exception		oduct?	INO		Provide sour	ce manufacturer for re	ераскадеа product	Box/Carton/Bu	indie/					
If yes, attach documentation fron	II FDA.							Case:						
		e-	TIN AND HIBCC PRODUCT I	NEORMATION				Case.	8.55	14.5	10	5	725	24
		0	THE AND THECCT RODUCT I	NI ORMATION				Pallet:						
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTII	N-14	Unit of Use GTIN-14	anet.						
X Item/Each	3	1				31722288101	5 5. 556 61111 14							
Box/Carton/Bundle/Inner Pack							COST INFORMATION			WHOLESALER USE ONLY:				
X Case		24			103	31722288108								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WAC) (\$)	\$154.22	Whsl. Code	#:		
											Fineline Cod	de:		
								As of date:	3/13/2023					
]													
1								11			ļ			
l		_	Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza		SERT, LABEL AND PHOTO OF I	PRODUCT PACKA						
*Please provide any additional info	ormation on page	2.				See new n 3 for De	signated Drop Ship Only.		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 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?					