

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

Version 2021						Introduction 7	Гуре:	New Item		x	inal Version			Date:	4/5/	/2023
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIRE					REMENTS*				
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						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 – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applical	ble:															
DUNS:	82-677-4775										perature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Lev	othyroxine Sodium Tablets USF	, 75mcg						(writ	e in)					
Selling Unit NDC: UDI	31722-286-10		Unit of Use NDC: CVX Code:			UPC: MVX Code:	33172	2286107		Notes						
Description: Levothyroxine Sodium Tablets USP, 75mcg										to customers on i			No No	-		
Active Ingredient(s): Levothyroxine Sodium								is this pro	auct to be snipped	to customers on o	iry ice?		INO			
							b. Contact for temperature excursion questions:									
URL for Additional Product Information: www.camberpharma.com							Name: Soma Raju									
Address:		Ave (and) 800 Cer	ntennial Ave, Suite 1			Address 2:			Number:			732-529-0423				
City:				State:	NJ Zip: 08854			Group E-mail:				somaraju@heterousa.com				
Key Contact:	Customer Service 1-866-827-3647				Email: Fax:	customerservice@camberpharma.com 732-562-8788			- 6						No	7
Phone Number: Product Therapeutic Classification		Synthetic Thyroid Hormone			rax.	732-302-0700			c. Special regulations for product in any states? Special returns requirements for this product?				No			
Froduct Therapeutic Classificatio	11.	Synthetic Thyron	a Homione							Special re	iums requirement	s for this product?			INU	
	ADDITI	ONAL PRODUCT	INFORMATION			PRODUCT	DESCRI	IPTION INFORMATION	d. Store prod	luct (unit of	sale) upright?				No	٦
The product is?			Is the Product	Direct-Ship C	nly				a. o.o.o p. oo		oduct (unit of sa	la) from light?			No	=
a legend device?		No	Is the Product	Neither	Jilly			1000ct	e. Shelf life:	rrotect p	oduct (unit or sa	ile) iroin light?			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:		100001	0. 0	Initial she	If life at launch (i	if different):				Months
a product kit?		No				Strength:		75mcg						_		
if yes, list NDCs of	FDA Approval Status				Suengui.			ORDER INFORMATION								
component parts						Dosage Forn	m:	Tablet		11-21-40-	1-		\A/l= =4 != 4l= =	NDC selling		
reverse numbered? co-licensed?		No No	Allergens Present							Unit of Sa	il e Bottle		1 bottle of 1		unitr	
latex-free?		Yes	Allergens Present					capsule shaped, biconvex			Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Sha	ipe:	tablets			Ampule		(g		
correctional institution block?		No				Product Cole	or.	Violet			Glass		Minimum o	rder quantity	y?	Yes
opioid?		No				1 Todact Con	o				Гube					
Cannabinoid?		No	Country of Origin	USA		Product Imp	rint:	plain on one side and debossed			/ial Liquid Sgl		W. V 1			
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered up	nder the				"score line 3" on the other			/ial Liquid Multi /ial Powder Sql			many of wh	ich package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		Yes			side.			/ial Power Multi		24	Inner/Cartor	n/Pack	
in Unit Dose, indicate NPO nere.									Other: Write In			Case	,, doit			
			FOR GENERIC DRUG PRO	DDUCTS										-		
					Au	thorized Generic		horized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB4				section fields are not applicable			Rec. sell unit	to custom	er?	1	Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Thyro-Tabs							OM/site in a s	4 \/:=!\				Each Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMAT				RMATION								Milliliter				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION												Ivillilitei				
Does supplier meet DSCSA defini	ition of manufactur	rer?	Yes		GLN:	0331722000000					ITEN	I AND PACKING II	NFORMATIO	N		
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:						Weight Lbs.	Dimensi	ons (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:											Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		10	No Yee	_		riginal product pur	chased		Item/Each:		0.33	2.25	2.25	4.25	21.52	1
Is product sold by manufacturer's Has FDA granted waiver/exception			Yes No	+	direct from m	nfr? ce manufacturer fo	or ronan	kaged product	Box/Carton/E	Rundle/						
If yes, attach documentation from		oddet:	140		r rovide sour	ce manuracturer re	лтерас	kageu product	Inner Pack:	Juliule/						
, , , , , , , , , , , , , , , , , , , ,									Case:		8.45	14.5	10	5	725	24
		(GTIN AND HIBCC PRODUCT IN	IFORMATION							0.45	14.5	10	5	725	24
									Pallet:							
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14		Unit of Use GTIN-14								
X Item/Each Box/Carton/Bundle/Inner Pack							WHOLESALER USE ONLY:									
X Case		24			103	31722286104				000.	INFORMATION				211 002 011	
Pallet									Regular Cost	t			Vendor #:			
									Invoice Cost			\$147.89	Whsl. Code			
											1/5/0000		Fineline Co	de:		
	-								As of date:	Ľ	1/5/2023		ļ.			
 			Attack convet CAFETY DA	TA QUEET (QF	C) or non hozo	rd letter DACKAGE	INICED	T, LABEL AND PHOTO OF P	RODUCT PACK	AGING and	BARCODE					



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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: 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) 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 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?