

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

Version 2021					Introduction 1	Туре:	New Item		x Final Ve	ersion			Date:	4/5/2	2023
		PRODUC	T INFORMATION						SPE	CIAL HANI	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals. Inc.				Applica	Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANI				215259				ui romporata	Temperature Ran		Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab									·						
DUNS:	82-677-4775								Other Temperatu	re Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Name:	Levothyroxine Sodiur		cg				[(write in)						
Selling Unit NDC:	31722-293-10		of Use NDC:		UPC:	33171222	93105		Notes						
UDI		CV	Code:		MVX Code:										
Description:	Levothyroxine Sodium Tab	ets USP, 175mcg						ĺ			I to customers on i			No	
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Levothyroxine Sodium															
URL for Additional Product Information: www.camberpharma.com b. Contact for temperature excursion questions: Name: Soma Raju															
Address:	formation: www.camberpharma.com 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:			Number:				732-529-0423			
City:	Piscataway			State:	NJ Zip: 08854			Group E-mail:				somaraju@heterousa.com			
Key Contact:	Customer Service			Email:	customerservice@camberpharma.com									_	
Phone Number:	1-866-827-3647			Fax:	732-562-8788			c. Special reg	ulations for produ	uct in any	states?			No	
Product Therapeutic Classification	n: Synthet	c Thyroid Hormone							Special returns re	quirements	s for this product?			No	
								.1							
	ADDITIONAL PR	ODUCT INFORMATION			PRODUCT	DESCRIPT	ION INFORMATION	d. Store prode	uct (unit of sale) u	pright?				No	
The product is?		Is the Proc		-Ship Only		_			Protect product	(unit of sa	le) from light?			No	
a legend device?	No	Is the Proc		er	Size:	10	00ct	e. Shelf life:						24	Months
if yes, enter class #		Orphan Dr	ig Status				_		Initial shelf life a	t launch (i	f different):				Months
a product kit?	No	FDA Appro	val Status		Strength:	17	5mcg				ORDER INFORM				
if yes, list NDCs of component parts		FDA Appro	vai Status			Та	blet				OKDEK INFORM	ATION			
reverse numbered?	No				Dosage Form	m: 1ª	biet		Unit of Sale			What is the	NDC selling	unit?	
co-licensed?	No	Allergens	resent						x Bottle			1 bottle of 10			
latex-free?	Yes				Product Sha	ca	psule shaped, biconvex		Box/Ca	rton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?	No				FIGUUCI SHA	tab	olets		Ampule						
correctional institution block?	No				Product Col	lor:	ac		Glass			Minimum o	der quantity	?	Yes
opioid?	No								Tube						
Cannabinoid?	No	Country of	Drigin USA		Product Imp		in on one side and bossed "1 score line 0"		Vial Liq Vial Liq			K Vaa haw	many of whi		
If Unit Dose, is item bar coded to u hospital scanning?	Init dose for	Is this prod	ict covered under the				the other side.		Vial Po				Each	ch package i	type ?
If Unit Dose, indicate NDC here:			ements Act (TAA)?	Yes						wer Multi		27	Inner/Carton	/Pack	
		J	,						Other: V				Case		
		FOR GENER	C DRUG PRODUCTS	S				·							
				A	uthorized Generic		ized Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4					section fie	elds are not applicable	Rec. sell unit	to customer?			Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bran	nd?: Thyro-T	abs											Each		
	DE	UG SUPPLY CHAIN SEC						(Write-in, e.g.	1 Vial)				Gram Milliliter		
	Dr	UG SUFFLT CHAIN SEC	JKITTACT (DSCSA)	INFORMATION				-					winniner		
Does supplier meet DSCSA definit	tion of manufacturer?	Yes		GLN:	0331722000000					ITEM	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?		No													
If yes, select exemption:				GCP:				1			Dimensi	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:									Weig	ht Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No		If yes, was o	riginal product pur	rchased		Item/Each:).33	2.25	2.25	4.25	21.52	1
Is product sold by manufacturer's		Yes		direct from r							2.20	2.20	4.20	21.02	
Has FDA granted waiver/exception		No		Provide sou	rce manufacturer fo	or repackaç	ged product	Box/Carton/B	undle/						
If yes, attach documentation from	n FDA.							Inner Pack: Case:							
		GTIN AND HIBCC	PRODUCT INFORMA	ATION				Case.		8.5	14.5	10	5	725	24
								Pallet:							
Saleable Unit of Measure	Saleable C	uantity HIBCC			IN-14	L	Init of Use GTIN-14								
X Item/Each	1			003	331722293105										
Box/Carton/Bundle/Inner Pack						_			COST INFOR	MATION			WHOLESALE	ER USE ONL	Y:
X Case	24			103	331722293102	-		Bogular Cr.				Vendor #:			
Pramet						-		Regular Cost Invoice Cost	(WAC) (\$)		\$222.11	Vendor #: Whsl. Code	# ·		
						-		intoice cost (······································		φ200.11	Fineline Co			
						-		As of date:	4/5/202	3					
												1			
μ												<u> </u>			
		Attach copy o	SAFETY DATA SHE	ET (SDS) or non haz			ABEL AND PHOTO OF P	PRODUCT PACKA		DDE.					
*Please provide any additional info	ormation on page 2.				See new p. 3 for	r Designate	d Drop Ship Only.		Signature:						

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

Version 2021 For Des	signated Drop Ship Only Products, Please Use Page 3
MATERIA	L HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? N b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? N Is the product a CA Prop 65 reproductive toxicant? N Does the product label bear a CA Prop 65 warning? 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? N	o x Organic Corrosive o Inorganic Oxidizer o Steroid/Androgen Contact Hazard o Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Storage Level:
e. Does the product contain DET if it is product regulated for shipment by DOT? 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 c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	o EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? No 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	o Med Guide Required No Limited Distribution Requirement Image: Comments / Details: (For example, iPledge program?) Image: Comment of the second secon
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) Special Permit; DOT-SP	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:
Special Provision (listed in Column 7 of 49 CFR 172.101);	Parister No.
SP#ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS
Controlled by State(s)? ARCOS Reportable? Schedule No. No CLASS OF TRADE RESTRICTION: No No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	contact - customerservice@camberpharma.com
No resultation: seed Yes if sold or fetal pharmacy, nospitals, cuinces and physician offices If the second seed Yes if sold or fetal pharmacy, nospitals, cuinces and physician offices Restricted to retail pharmacy only: N Restricted to hospital, clinics, and physician offices only: N Restricted from US territories? (explain in comments) N Comments: Image: Comments in the second s	O Special regulations or returns requirements for this o product in certain states?
MISCEL	ANEOUS NOTES and/or Image of Product Barcode:



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Version 2021 FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	not a designated drop ship, do not complete.
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?