

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

Version 2021						Introduction 1	Туре:	New Item		x Final Versi	n		Date:	4/5/	/2023	
			PRODUCT INFORMAT	TION						SPECIA	L HANDLING AND ST	ORAGE REQU	IREMENTS*			
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 applicable:																
DUNS:	82-677-4775									Other Temperature F	ange Requirement					
Proprietary Name (If Applicable) a		ame: Levo	othyroxine Sodium Tablets USF	P, 175mcg						(write in)						
Selling Unit NDC: UDI	31722-293-90		Unit of Use NDC: CVX Code:		31722-293-90	UPC: MVX Code:	33172	22293907		Notes						
-																
Description: Levothyroxine Sodium Tablets USP, 175mcg							Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice? No									
Active Ingredient(s): Levothyroxine Sodium							·	is this product to be	mpped to customers d	n ary ice?		INO				
Active ingredient(s).							b. Contact for temperature excursion questions:									
URL for Additional Product Information: www.camberpharma.com					_			Name: Son				l				
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:			Number:				732-529-0423				
City:		Piscataway State:				NJ		08854	Group E-mail: somaraju@heterousa.com					<u>m</u>		
Key Contact:	1-866-827-3647	9			Email: Fax:	customerservice@camberpharma.com 732-562-8788			a Cuasial va					No	7	
Phone Number: Product Therapeutic Classification		-827-3647 Synthetic Thyroid Hormone			rax:	732-302-0700			c. Special regulations for product in any states? Special returns requirements for this product?			40	No			
Product Therapeutic Classificatio	n:	Synthetic Thyrold	nomone							Special returns requi	ements for this produc	ıır		INO		
	ADDITI	ONAL PRODUCT I	INFORMATION			PRODUCT	DESCR	RIPTION INFORMATION	d Store prod	luct (unit of sale) upri	aht?			No	7	
The product is?			Is the Product	Direct-Ship (Only						t of sale) from light?			No	1	
a legend device?		No	Is the Product	Unit of Use	Silly			90ct	e. Shelf life:	Protect product (un	t or sale) from light?			24	Months	
if yes, enter class #		140	Orphan Drug Status			Size:		3001	c. Onen me.	Initial shelf life at la	unch (if different):			2-7	Months	
a product kit?		No				Strength:		175mcg								
if yes, list NDCs of			FDA Approval Status			Strength.			ORDER INFORMATION							
component parts						Dosage Form	m:	Tablet								
reverse numbered? co-licensed?		No	Allaumana Duagant							Unit of Sale x Bottle		1 bottle of 9	e NDC selling	j unit?		
latex-free?		No Yes	Allergens Present					capsule shaped, biconvex		x Bottle Box/Carton			e.g. 1 Box of 1	In Vials)		
preservative-free?		No				Product Sha	ape:	tablets		Ampule		(vviite iii, t	J.g. 1 DOX 01	io viais)		
correctional institution block?		No				Product Col		Lilac		Glass		Minimum o	order quantit	y?	Yes	
opioid?		No				Product Col	or:			Tube			-	-		
Cannabinoid?		No	Country of Origin	USA		Product Imp	rint:	plain on one side and		Vial Liquid						
If Unit Dose, is item bar coded to u	unit dose for		In this was dead account to	a deserth a				debossed "1 score line 0" on the other side.		Vial Liquid				ich package	type?	
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (T		Yes			on the other side.		Vial Powde Vial Power		24	Each Inner/Carto	n/Pack		
ii Oliit Dose, ilidicate NDC liele.			Trade Agreements Act (1	701):	163					Other: Writ			Case	II/I ack		
			FOR GENERIC DRUG PRO	ODUCTS												
					Au	thorized Generic		thorized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB4					section fields are not applicable			Rec. sell unit to customer?			Rx billing	Rx billing unit to pharmacy:			
II. Generic Equivalent to What Bra	ind?:	Thyro-Tabs											Each			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g	. 1 Vial)			Gram					
		DRUG SUPI	PLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION				Milliliter							
Does supplier meet DSCSA defini	ition of manufactur	rer?	Yes	7	GLN:	0331722000000					ITEM AND PACKING	3 INFORMATIO	ON			
Is product exempt from DSCSA?			No	-		2232200000										
If yes, select exemption:					GCP:						Dime	nsions (US ms	mts.)	Volume	Saleable #	
Other exemption - Write in:										Weight	.bs. Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No			iginal product pur	chased	d	Item/Each:	0.08		2.5	3	18.75	1	
Is product sold by manufacturer's			Yes	_	direct from m	fr?					, 2.0	2.0	3	10.70	1	
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	or repac	ckaged product	Box/Carton/E	Bundle/						
If yes, attach documentation from	m FDA.								Inner Pack: Case:							
		G	TIN AND HIBCC PRODUCT IN	FORMATION					Case.	2.35	10	7	4.25	297.5	24	
									Pallet:							
Saleable Unit of Measure	8	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14								
X Item/Each		1			003	31722293907		00331722293907								
Box/Carton/Bundle/Inner Pack				2470000000	_		COST INFORMATION				WHOLESALER USE ONLY:					
X Case Pallet		24			103	31722293904	-		Regular Cos			Vendor #:				
Fallet					-		-		Invoice Cost		\$20	98 Whsl. Cod	o #-			
											φ20.	Fineline C				
									As of date:	4/5/2023						
1									Ц							
ĺ	formation on name		Attach copy of SAFETY DA	TA SHEET (SI	DS) or non haza			RT, LABEL AND PHOTO OF F	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: 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?					