

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

Version 2021						Introduction Type	e: New Item		x Final Version			Date:	6/23	/2024
			PRODUCT INFORMA	TION					SPECIAL HAI	NDLING AND STOR	RAGE REQUI	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		and 25 C (68	3° – 77° F)		
Medical Device Class, if applicable:														
DUNS:	11-856-3719							_	Other Temperature Range	Requirement	Excursions a	allowed betwe	een 15° and 3	30°C (59°
Proprietary Name (If Applicable) a		ame: Levo	thyroxine Sodium Tablets, US						(write in)		and 86°F)			
Selling Unit NDC:	31722-285-10		Unit of Use NDC:				31722285100		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Levothyroxine So	dium Tablets, USP	50 mcg						Is this product to be shippe	d to customers on i	ce?		No	
									Is this product to be shipped	d to customers on o	dry ice?		No	
Active Ingredient(s): Levothyroxine sodium, USP							11							
URL for Additional Product Information: www.camberpharma.com						b. Contact fo	or temperature excursion qu	estions:	Soma Raju					
Address:	800 Centennial A		na.com		1	Address 2:		-	Name: Number:		732-529-042	23		
City:	Piscataway					Zip: 08854	-	Group E-mail:			neterousa.com	m		
Key Contact:	Customer Service					camberpharma.com				<u>oomaraja o</u>	101010404.00	<u></u>		
Phone Number:	1-866-827-3647				732-562-8788		c. Special regulations for product in any states?			No				
Product Therapeutic Classification	n:	Synthetic thyroid h	normone						Special returns requiremen	its for this product?			No	
_					-									_
	ADDITI	ONAL PRODUCT I	NFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store product (unit of sale) upright?						
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of s	ale) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	1000 ct	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:	50 mcg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	MATION			
component parts reverse numbered?		NI.				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present						x Bottle		1 Bottle of 1		uiiit:	
latex-free?		Yes					Capsule, biconvex		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No	Alcoh	ol, Sugar		Product Shape:	,		Ampule		(3	- 11	
correctional institution block?		No				Product Color:	White		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint	Plain on one side and debossed 'score line 2' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for								Vial Liquid Multi				ich package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered to Trade Agreements Act (Yes				Vial Powder Sgl Vial Powder Mult		24	Each Inner/Cartor	·/Deals	
Il Ollit Dose, ilidicate NDC liele.			Trade Agreements Act (174):	res				Other: Write In			Case	// aux	
			FOR GENERIC DRUG PR	ODUCTS								1		
					Au	thorized Generic *If	f Authorized Generic, other		Р	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4					se	ection fields are not applicable	Rec. sell uni	it to customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	nd?:	Thyro-Tabs						T				Each		
								(Write-in, e.g. 1 Vial) Gram						
		DRUG SUPF	PLY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION							Milliliter		
Does supplier meet DSCSA defini		2	Yes	_	GLN:	0331722498975			ITC	M AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	tion of manufactu	rer?	No	_	GLN:	0331722496975			116	W AND FACKING I	NFORMATIO	N.		
					000					Dime	ions (US msn	ato \	14-1	0-1
If yes, select exemption: Other exemption - Write in:					GCP:				Weight Lbs.	Dimens	ions (US msn Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes was o	riginal product purcha	hazi	Item/Each:		1			T .	
Is product sold by manufacturer's	exclusive distribu	utor?	Yes		direct from m			1.0	0.34	2.25	2.25	4.25	21.52	1
Has FDA granted waiver/exception			No			ce manufacturer for re	epackaged product	Box/Carton/	Bundle/					
If yes, attach documentation from	m FDA.							Inner Pack:						
								Case:	8.55	14.5	10	5	725	24
		G	TIN AND HIBCC PRODUCT I	NFORMATION				Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		CTI	N-14	Unit of Use GTIN-14	Pallet:						
X Item/Each		1	ПВСС			31722285100	Offic of Ose G file-14							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			103	31722285107								
Pallet	_							Regular Cos	st .		Vendor #:			
								Invoice Cost	t (WAC) (\$)	\$144.67	Whsl. Code			
								11.	0// 0/0000		Fineline Co	de:		
								As of date:	3/13/2023					
 			Attach conv of SAFETY D	ATA SHEET (ST	S) or non haza	ard letter PACKAGE INI	SERT, LABEL AND PHOTO OF	PRODUCT PACE	(AGING and BAPCODE		1			
*Please provide any additional inf	ormation on page	2.	, addit dopy of OAI ETT DI	OFFEET (OL	. C / OI 11011 11dZd		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 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?					